IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow for the Use and Benefit of Herself and the Next of Kin of RICHARD SMITH, Deceased,	)	**Case #: 3:05-00444**
	)	**Judge Trauger**
Plaintiff,	)	
-against-	)	
PFIZER INC., PARKE-DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY LLC and JOHN DOE(S) 1-10,	)	
Defendants.	)	

PLAINTIFF'S OBJECTIONS TO DEFENDANTS' EXPERT STATEMENTS

Plaintiffs make the following general objections to Defendants' Witness Statements.

- Defendants' Expert Statements are unduly duplicative. Defendants have provided statements for 3 specific causation experts. Defendants should not be allowed to proffer repetitive witness statements from this many specific causation experts.

- Defendants' Expert Statements are filled with anecdotal evidence based upon their experience with Neurontin. These repeated anecdotes framed around their "personal experience" are unreliable per Rule 702.

1. Peter Donofrio, MD (specific causation expert)

Page: Line	***Statement***	***Objection***
4:1	"Neurontin is a safe and effective treatment for neuropathic pain, and is widely regarded in neurology as one of the most useful medication options for treating chronic neuropathic pain."	Rule 702. Neurontin is not approved for the indication of "neuropathic pain" in the U.S; therefore it cannot be said to be "safe and effective". Neurontin is approved only for the limited indication of post-herpetic neuralgia and treatment of epilepsy. Use of the terms "safe and effective" is a legal term, beyond the scope of the witness's expertise, the

		definition being governed by the FDA's requirements for a new drug to be proven "safe and effective" before being marketing in the U.S. Relevance. Dr. Donofrio is a case-specific expert and so the issue is whether Neurontin contributed to Mr. Smith's suicide, not whether Dr. Donofrio has an opinion that Neurontin has benefits. Probative value is outweighed by prejudice.
5:5-7	"I have never relied on detailing or advertising from pharmaceutical companies or their sales representatives when deciding whether to prescribe a medication."	Relevance. Probative value is outweighed by prejudice.
5:7-9	"And I should add that no one from Pfizer or Warner-Lambert has ever promoted the off-label use of Neurontin to me or in an educational forum that I have attended."	Relevance. Probative value is outweighed by prejudice.
5:10-11	"Based on all those considerations, in my opinion Neurontin is a safe and effective treatment for neuropathic pain."	Neurontin is not approved for the indication of "neuropathic pain" in the U.S; therefore it cannot be said to be "safe and effective." Neurontin is approved only for the limited indication of post-herpetic neuralgia and treatment of epilepsy. Use of the terms "safe and effective" is a legal term, beyond the scope of the witness's expertise, the definition being governed by the FDA's requirements for a new drug to be proven "safe and effective" before being marketing in the U.S.
5:22 – 6:4	"In my own clinical experience, Neurontin can be effective in relieving neuropathic pain in doses as low as 100mg twice or three times per day, but this is not common…. I have prescribed up to 4,800 mg/day with success …. Mr. Smith's dosage at the time of his death was 900mg/day which is well below the dosage that most patients need to see meaningful relief."	Relevance – Dr. Donofrio's "clinical experience" is irrelevant and unreliable per Rule 702. If Dr. Donofrio's experience is relevant, are other expert's experience treating people with suicidal ideation after taking Neurontin also admissible ?

7:10-11	"In European countries, Neurontin and other drugs have been approved by drug-regulatory agencies for "neuropathic pain" in general."	Relevance. Probative value is outweighed by prejudice.
8:5-7	"In my opinion, the labeling for neurontin that was in effect in 2004 when Mr. Smith was prescribed Neurontin was adequate to warn physicians of the risks and benefits of using the medication."	Rule 702, and the opinion is beyond the witness's expertise. The opinion is also untimely to the extent it is a general causation opinion governed by the MDL schedule for expert disclosures. Dr. Donofrio's expert disclosure was allowed only as a case-specific expert disclosure, and thus is to be limited to the issue of whether Neurontin contributed to Mr. Smith's suicide; instead, Dr. Donofrio provides a general causation opinion. The opinion is duplicative of Defendants' general causation/liability experts who previously provided expert disclosures in accordance with the MDL's scheduling order relating to general expert opinions (e.g., Arrowsmith-Lowe, Jacobs, Rothschild, Ruggieri). The opinion also seeks to merely bolster the opinion of Defendants' aforementioned general causation/liability experts. Probative value outweighed by prejudice.
8:11-13	"No patient has ever reported suicidality to me in connection with his or her Neurontin use and I am not aware of any patient of mine committing suicide while taking Neurontin."	Relevance. Probative value outweighed by prejudice.
8:14-21	"There is no convincing and reproducible scientific data supporting a conclusion that Neurontin causes suicide. The meta-analysis conducted by the FDA of 11 different anti-epileptic drugs does not prove that Neurontin	Rule 702. The opinion is also untimely to the extent it is a general causation opinion governed by the MDL schedule for expert disclosures. Dr. Donofrio's expert disclosure was allowed only as a case-specific expert disclosure, and thus

	causes suicidality. In fact, the Neurontin-specific data in the FDA's report specifically show that there is no statistically significant increased risk of suicidality with Neurontin use. The work done by Dr. Robert D. Gibbons, PhD, confirms that the data show no increased risk of suicidality in patients who take Neurontin. In my opinion, there was never any basis for Pfizer to have changed the labeling that FDA had approved in 1993 and 2002 to add information or warnings about suicidality."	is to be limited to the issue of whether Neurontin contributed to Mr. Smith's suicide; instead, Dr. Donofrio provides a general causation opinion. The opinion is duplicative of Defendants' general causation experts who opine that Neurontin generally cannot contribute to suicide. The opinion also seeks to merely bolster the opinion of Defendants' expert, Gibbons, PhD, who provided Defendants' general causation opinion regarding statistics/epidemiology. Probative value is outweighed by the prejudicial effect.
9:1	"[I]t is my opinion that Neurontin is a safe and effective medication . . ."	Neurontin is not approved for the indication of "neuropathic pain" in the U.S; therefore it cannot be said to be "safe and effective." Neurontin is approved only for the limited indication of post-herpetic neuralgia and treatment of epilepsy. Use of the terms "safe and effective" is a legal term, beyond the scope of the witness's expertise, the definition being governed by the FDA's requirements for a new drug to be proven "safe and effective" before being marketing in the U.S.; Neurontin is not approved for the indication of "neuropathic pain" in the U.S; therefore it cannot be said to be "safe and effective." Neurontin is approved only for the limited indication of post-herpetic neuralgia and treatment of epilepsy. Relevance. Dr. Donofrio is a case-specific expert and so the issue is whether Neurontin contributed to Mr. Smith's suicide, not whether Dr. Donofrio has an opinion that Neurontin has benefits.

		Probative value is outweighed by the prejudicial effect.
11:4-5	"Mr. Smith had expressed the wish to die because of pain and depression, before he ever used an Neurontin . . ."	Lacks foundation. Hearsay. Probative value outweighs prejudice.
12:6-10	"March 1, 2004. The Police Report prepared shortly after his death indicates that on March 1, Mr. Smith had expressed suicidal ideation to his daughter, Cindy Smith, similar to the remarks made in May of the preceding year about 'wishing he could die because of pain and depression." Again, Mr. Smith had not taken Neurontin by this time."	Hearsay. Probative value outweighed by the prejudicial effect.
12:18	[Prior to taking Neurontin, Mr. Smith] "...had already expressed suicidal thoughts on at least two occasions…"	Hearsay; Objection to reference of prior suicidal thoughts without foundation. Probative value outweighed by prejudice.
13:27	"all along before he ever used Neurontin."	Hearsay; Objection to reference of prior suicidal thoughts without foundation; probative value outweighed by prejudice.
15:16-22	"Even if we assume Richard Smith had been taking the medication as prescribed, in my clinical judgment, his dose may have been too low to offer him any relief from his pain. Mr. Smith was prescribed a low dose of Neurontin --- 600 mg/day to 900 mg/day, as compared with the effective dosage range reported in the labeling for Neurontin of 1800-3600 mg/day. It is likely that this dose was sub-therapeutic for him and that he was not achieving adequate pain relief from this dose of Neurontin or from his other pain medications. This opinion is supported both by my clinical experience and the published, peer-reviewed neurological literature.	Rule 702. The opinion lacks methodology or reliability in that there is no basis for the opinion that Neurontin is "effective" at any dose, whether 600–900 mg/day or 1800-3600 mg/day, unless the use is for an approved use (e.g., epilepsy or post-herpetic neuralgia). Consequently the opinion about Mr. Smith's dose being sub-therapeutic is without basis. Probative value is outweighed by prejudice.

Objections to Dr. Donofrio's Slide/Exhibits

Doc. No., Page	***Statement***	***Objection***
73-2, p. 1	"Neurontin is a safe and effective treatment for neuropathic pain . . ."	Rule 702. Neurontin is not approved for the indication of "neuropathic pain" in the U.S; therefore it cannot be said to be "safe and effective". Neurontin is approved only for the limited indication of post-herpetic neuralgia and treatment of epilepsy. Use of the terms "safe and effective" is a legal term, beyond the scope of the witness's expertise, the definition being governed by the FDA's requirements for a new drug to be proven "safe and effective" before being marketing in the U.S. Relevance. Dr. Donofrio is a case-specific expert and so the issue is whether Neurontin contributed to Mr. Smith's suicide, not whether Dr. Donofrio has an opinion that Neurontin has benefits. Probative value is outweighed by prejudice.
173-2, p. 1	"The labeling, or professional package insert, for Neurontin approved by FDA at the time of Mr. Smith's death adequately communicated the potential benefits and risks of Neurontin to doctors."	Rule 702. The opinion is also untimely to the extent it is a general causation and/or general liability opinion governed by the MDL schedule for expert disclosures. Dr. Donofrio's expert disclosure was allowed only as a case-specific expert disclosure, and thus is to be limited to the issue of whether Neurontin contributed to Mr. Smith's suicide; instead, Dr. Donofrio provides a general liability opinion regarding whether Defendants failed to warn. The opinion is also beyond the scope of the witness's purported expertise. The opinion is duplicative of Defendants' general causation/liability

		experts whose opinions were previously disclosed during the general MDL disclosure period (e.g., Jacobs, Rothschild, Arrowsmith-Lowe, and Ruggieri). The opinion also seeks to merely bolster the opinions of Defendants' general liability experts. Probative value is outweighed by the prejudicial effect.
		Use of the terms "safe and effective" is a legal term, beyond the scope of the witness's expertise, the definition being governed by the FDA's requirements for a new drug to be proven "safe and effective" before being marketing in the U.S.; Neurontin is not approved for the indication of "neuropathic pain" in the U.S; therefore it cannot be said to be "safe and effective." Neurontin is approved only for the limited indication of post-herpetic neuralgia and treatment of epilepsy. Relevance. Dr. Donofrio is a case-specific expert and so the issue is whether Neurontin contributed to Mr. Smith's suicide, not whether Dr. Donofrio has an opinion that Neurontin has benefits. Probative value outweighs the prejudicial effect.

2. Douglas Jacobs, MD (general/specific causation expert)

Page: Line	***Statement***	***Objection***
6:17	"The FDA, the regulatory authority that oversees pharmaceuticals, has not determined that Neurontin causes suicide."	Rule 702. Use of the terms "causes" is a legal term, beyond the scope of the witness's expertise, in terms of testifying to the FDA regulatory definition for causation.

7:19--8:8	"Another concept that is important but at times challenging to understand is statistical significance. Briefly, statistical significance is the measure of how likely it is that the observed difference is real or caused by random chance….Despite what you have heard about the FDA's meta-analysis of anti-epileptic drugs, if one looks specifically at Neurontin, which is the anti-epileptic drug in this case, the placebo controlled data for Neurontin do not indicate any increase in suicidal thoughts or actions in patients treated with Neurontin versus placebo.	Rule 702. The opinion is beyond the scope of the expert's reports and deposition testimony. This opinion has not been previously propounded by this expert. The opinion is <u>duplicative</u> of Defendants' general causation expert, Gibbons, PhD, who was specifically retained by Defendants and granted leave by the MDL Court (Hon. Patti Saris) to opine on the FDA Alert and meta-analysis. The opinion also seeks to merely bolster the opinion of Defendants' expert, Gibbons, PhD, who provided Defendants' general causation opinion regarding statistics/epidemiology. Probative value is outweighed by the prejudicial effect.
8:9—9:15	"In June of 2006 Pfizer provided a report to the FDA on suicide events in all of Pfizer's controlled trials in response to the FDA's request for information on anti-epileptic drugs and suicide. As the report states, in the table shown here, in the Neurontin trials, which involved 5,194 patients, importantly there were no patients who either committed or attempted suicide. Even looking at suicidal ideation, which is thinking about suicide, the rates were basically identical in the Neurontin and placebo treated patients. Specifically, .039% of Neurontin patients and .037% of placebo patients reported suicidal thoughts. Thus, there is no statistically meaningful difference between these rates, leading to the conclusion of not increased risk of suicide. Furthermore the controlled trials provided no indication that Neurontin increased the risk of depression or	Rule 702. The opinion is beyond the scope of the expert's reports and deposition testimony. This opinion has not been previously propounded by this expert. The opinion is <u>duplicative</u> of Defendants' general causation expert, Gibbons, PhD, who was specifically retained by Defendants and granted leave by the MDL Court (Hon. Patti Saris) to opine on the FDA Alert and meta-analysis. The opinion also seeks to merely bolster the opinion of Defendants' expert, Gibbons, PhD, who provided Defendants' general causation opinion regarding statistics/epidemiology. Probative value is outweighed by the prejudicial effect.

	anxiety. There have been at least 3 well controlled trials studying Neurontin with panic disorder, bipolar disorder and social phobia. Those studies use the gold standard method for measuring depression and anxiety referred to as the Hamilton Depression and Hamilton Anxiety scales. There was not any statistical difference between the Neurontin treated group and the placebo group in scores on either of those scales in any of the 3 studies meaning that Neurontin is not associated with, and does not cause or worsen, depression or anxiety. Importantly, the FDA alert does not state that the anti-epileptic drugs cause depression or anxiety. The alert was specific for suicidality, but as I said earlier this would not be true for Neurontin. To summarize, the FDA's pooled analysis of controlled data on 11 different anti-epileptic drugs including Neurontin, which led the FDA to impose additional suicide warning requirements for all anti-epileptic drugs does not alter my conclusions. As I have said, that analysis did not find a statistically significant increase for Neurontin itself. Furthermore, the FDA did not find an established causal mechanism between any of the anti-epileptic drugs, much less Neurontin itself in suicidal thoughts or actions. I also rely on the analysis performed by Dr. Gibbons who demonstrated several additional reasons why the FDA's analysis does not provide reliable scientific evidence that Neurontin causes suicide."	Witness cites materials not cited in expert report, specifically the reliance to Dr. Gibbons report.
25:9-14	"I disagree with Dr. Trimble's reliance upon the FDA meta-analysis as proof that Neurontin causes suicide. In fact, the FDA meta-analysis does not conclude anti-epileptics are associated with suicide. Furthermore, the FDA	Rule 702. The opinion is beyond the scope of the expert's reports and deposition testimony. This opinion has not been previously propounded by this expert.

	meta-analysis pertains to 11 medications. When these 11 medications are considered separately, there is no evidence that Neurontin specifically causes suicide nor had a statistically significant increase in suicidality."	The opinion also seeks to merely bolster the opinion of Defendants' expert, Gibbons, PhD, who provided Defendants' general causation opinion regarding statistics/epidemiology. Probative value is outweighed by the prejudicial effect.
29:8-23	"In the pre-trial documents that I have reviewed, Dr. Maris had submitted a psychological autopsy form. I am highly critical of Dr. Maris's claims that this was supposed to provide scientific evidence concerning the cause of Mr. Smith's suicide. First, it was revealed in discovery that this form was filled out not by Dr. Maris, but by a legal assistant in the Plaintiff attorney's firm. This is totally unacceptable. During Dr. Maris's pre-trial deposition he attempted to correct some of the inaccuracies and omissions. For example, the form indicates that Mr. Smith was prescribed Lexapro for depression before starting Neurontin. The form indicates that Mr. Smith did not have any psychiatric diagnosis prior to starting Neurontin; again, this is simply incorrect. Dr. Cato diagnosed depression in May of 2003, again before Neurontin. The form does not acknowledge that Mr. Smith had pre-Neurontin suicidal ideation. Finally, the form does not make reference to Mr. Smith's pre-Neurontin history of depressive symptoms. In short, Dr. Maris's psychological autopsy was inaccurate, incomplete, but most importantly, unscientific."	Drafts of expert reports is an area for which the parties have agreed should not be questioned by the parties, as per the parties letter agreement, November 7, 2007 (included in Plaintiff's Pre-Trial Order Exhibits to the Court). Because the issue regarding Dr. Maris's draft "form" was a subject precluded from questioning and discovery, Defendants' experts should not be allowed to comment upon it at trial.

Objections to Dr. Jacobs's Slides/Exhibits

Doc. No., Page	***Statement***	***Objection***
177-2, p. 1	Demonstrative of Pfizer letter to FDA	Beyond the scope of Dr. Jacobs's Rule 26 disclosure; not previously disclosed by Dr. Jacobs.

3. Charles Taylor, PhD (general causation expert)

Page: Line	***Statement***	***Objection***
12:3	"The same experiment was repeated in human brain tissue taken from patients who had to have some tissue removed as part of brain surgery. Also, the study was repeated for the monoamine, noradrenaline, as well as from serotonin, and another neurotransmitter glutamate. The results in all those studies were similar to those in the Dooley study. Neurontin did not affect transmitter release at all, other than in a hyperexcited state, an in that case, it modulated, or reduced the amount of excessive transmitter release"	Rule 702, and the opinion is beyond the witness's expertise. Probative value is outweighed by prejudice.
19:15	"As I mentioned, that finding also was confirmed in human brain tissue and with other neurotransmitters, including serotonin."	Rule 702, and the opinion is beyond the witness's expertise.

4. Robert Granacher, MD (case-specific expert)

Page: Line	***Statement***	***Objection***
8:1-9	"My own opinion is that reliable scientific evidence that Neurontin causes suicide is lacking. I don't believe it does. In my profession, we see a number of patients with chronic pain conditions who develop depression or suicidal thoughts. That was true before Neurontin existed. That can happen regardless of how we treat severe chronic pain, and regardless of	Rule 702. The opinions are also untimely general causation/liability opinions for which the MDL court had already allotted Defendants a timeline for expert disclosure. In this case, Dr. Granacher's disclosure is allowed only as a case-specific opinion, to be limited to whether Neurontin proximately caused

	any particular type of medication we use. I have never seen anything in my own patients that even hinted that a patient developed depression or suicidal thoughts because of treatment with Neurontin. In my opinion, as a board certified psychiatrist who has prescribed Neurontin for years, the labeling for Neurontin – the package insert that is approved by FDA and issued by the manufacturer – has always had adequate information about the potential risks and benefits of the medication."	Mr. Smith's suicide. Consequently, Dr. Granacher's opinions as to general causation/liability (i.e., whether (1) Neurontin can contribute to suicidality, and (2) whether Defendants failed to warn) should be precluded.) The general causation/liability opinions are also beyond the scope of the witness's purported expertise. The opinions are duplicative of Defendants' general causation/liability experts whose opinions were previously disclosed during the general MDL disclosure period (e.g., Jacobs, Rothschild, Arrowsmith Lowe, and Ruggieri). The opinion also seeks to merely bolster the opinions of Defendants' general liability experts. Relevance. Dr. Granacher's anecdotal personal experiences as to a lack of his own patients experiencing suicidality is irrelevant and does not meet requirements of reliability for Rule 702. Dr. Granacher's opinion that the labeling for Neurontin adequately set forth "risks and benefits" also does not meet with Rule 702 or 403 because, as a matter of law, (a) Defendants' labeling for Neurontin did not have adequate "directions for use" for any off-label indication, as admitted by Defendants in their guilty plea for misbranding of Neurontin, and (b) the Neurontin labeling regarding risks and benefits applies only to the FDA approved indications for which the labeling applies. Probative value is outweighed by the prejudicial effect.

8:16-19	"In my opinion, the rule of parsimony should prevail in this case. The rule of parsimony dictates that the most reasonable and simplest explanation is, within reasonable medical probability, the best explanation. The most reasonable and simplest explanation for Mr. Smith's suicide is a chronic pain syndrome inducing depression."	Rule 702. Dr. Granacher provides no basis for his application of the "rule of parsimony" to meet the requirements of Rule 702 that such an applications is reasonable methodology or a reliable scientific application.
10:1-2	Suicidal Ideation: Mr. Smith's pain led to suicidal thoughts, which he expressed on at least two occasions before starting Neurontin.	Lack of foundation. Hearsay.
13:19-21	[Regarding the low Neurontin dose taken by Mr. Smith], "the FDA labeling recommends up to twice the dose that Mr. Smith was directed to take at this point."	Lack of foundation. The FDA labeling does not recommend any dose whatsoever related to the off-label pain condition for which Mr. Smith was prescribed Neurontin. Neurontin was only approved for the treatment of epilepsy and post-herpetic neuralgia (shingles). The FDA recommendations and the corresponding labeling are limited to the approved indications. Consequently, Dr. Granacher's testimony is false, misleading and will confuse the jury.
13:30-35	[Regarding Mr. Smith's statement to his dentist that Neurontin made him feel loopy] "According to the letter, Mr. Smith mentioned Neurontin, and said that it made him feel "loopy". We do not know what Mr. Smith meant by that remark. Whatever he meant by it, we cannot tell whether it was Neurontin, one of the other pain medications he was taking at that time, such as the opioid narcotic Lortab, or some other factor that made him feel that way."	Rule 702 and lack of foundation. Dr. Granacher provides no basis, methodology, or reliable scientific evidence to apportion causal association to other drugs (e.g., Lortab) ingested by Mr. Smith. His statements in this regard are speculative.
15:16-17	"In my opinion, the Lexapro was discontinued too soon. It takes six weeks for antidepressants to produce permanent improvement in depressive symptoms."	Rule 702, and lack of foundation. Dr. Granacher provides no basis, methodology, or reliable scientific evidence for this opinion. His statements in this regard are speculative.
15:17-20	"The discontinuance of Mr. Smith's Lexapro at six weeks after initiation,	Rule 702, and Lack of foundation. Dr. Granacher provides no basis,

	even with a positive response, likely led to relapse, as this is the usual effect of stopping antidepressant medication too soon."	methodology, or reliable scientific evidence for this opinion. His statements in this regard are speculative.
15:22-23--16:1-8	"Mrs. Smith testified that she did not know that her husband had been given antidepressants by Dr. Cato. From my point of view as a psychiatrist, that is an important fact. This shows Mr. Smith's reluctance to share the details of his depression or use of antidepressants even with his wife. Mr. Smith was not only a minister, but an elderly minister who came from a different era. Psychiatry and the ministry often did not mix. Mr. Smith was obviously resistant to discussing his psychological distress even with his wife, and resistant to seeking appropriate treatment for that distress. . . . . ….I have treated a number of priests, ministers, and seminary professors over the years, and in my experience, it is difficult for them to admit weakness and difficult for them to admit that G-d does not answer their prayers asking for relief from depression without medical assistance."	Rule 702. Speculation. Rule 702. Speculation based on Dr. Granacher's anecdotal experience.
20:17-20	"Police Report . . . According to the police report prepared immediately after Mr. Smith's suicide, which is shown in this demonstrative, one of Mr. Smith's daughters, Cindy Smith, told the investigating officer that Mr. Smith had mentioned to her that he might take his own life on March 1, 2004."	Hearsay. Probative value outweighed by prejudice.
22:2-3	[Dr. Granacher criticizes the effectiveness of Mr. Smith's antidepressants claiming that Mr. Smith was] "being treated with two antidepressants but not for a sufficient period of time to be effective…"	Rule 702 Lack of foundation. Speculation.
22:19-23	References to Mr. Smith's purported prior suicidal thoughts before ingesting Neurontin, including "statements about	Lack of foundation and hearsay as it relates to statements purportedly from Cindy Smith.

	depression and/or suicide made before he ever used neurontin appear in the medical records, police report, and medical examiner's report in this case."	

Objections to Dr. Granacher's slides/exhibits

Doc. No., Page	***Statement***	***Objection***
176-2, p. 2	Suicidal Ideation: Mr. Smith's pain led to suicidal thoughts, which he expressed on at least two occasions before starting Neurontin.	Lack of foundation. Hearsay.
176-2, p. 23	Metropolitan Police Report "On 3/1/04, the victim mentioned to his daughter, Cindy Smith, that he might take his own life."	Hearsay.

5. Plaintiff's Objections to the Proposed Testimony of Dr. Grabowski

A. Objections to Dr. Grabowski's testimony in its entirety:

1. Dr. Grabowski's opinions are exclusively legal opinions on the admissibility, methods and reliability of Dr. King's opinions, not on the Neurontin marketing evidence.

Dr. Grabowski does not offer any expert testimony on the issue of whether the Defendants' marketing and promotion of Neurontin was a substantial contributing factor that led to the off-label prescriptions of Neurontin for Richard Smith. Instead, his report, testimony, and opinions are solely directed at whether Plaintiff's marketing expert, Dr. Charles King's, opinions meet Federal Rules of Evidence, Rules 702–705. For example, his first two opinions are:

a. *Dr. King has provided no valid economic basis to conclude that off-label marketing of Neurontin indirectly influenced all, or substantially all, physicians prescribing Neurontin;* and

b. Dr. King's analysis does not provide that any specific Neurontin prescription was caused by any alleged misrepresentation by Defendants.

The balance of his opinions are the same — opinions directed at Dr. King's opinions, not at the evidence of Defendant's marketing and promotion of Neurontin. He neither formed nor expressed any opinions on jury fact issues.

The admissibility and sufficiency of evidence, including expert opinions, are matters of law and not issues of fact for the jury. The weight to be given to one expert's testimony is for the jury, not a subject for another expert witness's testimony.

Accordingly, Plaintiffs object to all of Dr. Grabowski's testimony as beyond the scope of expert testimony, Rule702, and not relevant or helpful to the jury, Rule 401, Rule 704.

2. **Dr. Grabowski did not review Defendants' marketing plans for Neurontin, Defendants' marketing documents, or the statistics of the Neurontin marketing and promotion programs.**

Dr. Grabowski did not review as part of his work any of the defendants' marketing documents. (*See* the list of records he considered, page 42, Grabowski expert report).

He made no effort to check the accuracy of the data in Dr. King's charts. (Deposition, p. 30). He did not do an economic, marketing, or econometric analysis himself to form an opinion whether Defendants' criminal marketing and promotion of Neurontin had a significant effect on doctors in writing off-label prescriptions of Neurontin. (Deposition, p. 45). He did no analysis to determine the extent, if any, of European approval or FDA approval for shingles may have influenced doctors to prescribe Neurontin off-label for neuropathic pain. (Deposition, p. 48). He did not analyze in any way whether the illegal promotion of Neurontin was a factor at all in off-label prescriptions. (Deposition, p. 57). He did no analysis of whether any off-label prescriptions for neuropathic pain were due to illegal marketing. (Deposition, pp. 71-72). He did not read the criminal Information by which the illegal marketing scheme to promote Neurontin was outlined and to which Defendants pleaded that the facts of the scheme were unequivocally true. (Deposition, p. 167).

He has no foundation for any expert opinion of the extent, duration, effect, or success of Defendants' marketing and promotion of Neurontin.

Plaintiff objects to his testimony as having no foundation, Rule 703.

3. **Dr Grabowski's proposed testimony is impermissible impeachment by opinion, the attempt to give various reasons why Dr. King is not credible, without evidence of either untruthfulness or of an underlying foundation error in facts.**

Dr. Grabowski's proposed testimony sharply criticizes Dr. King's opinions and methods without himself performing any of the studies he criticizes. He does not at any time find an error in Dr. King's statistics or in the final analyses and does not at any point undertake to determine what the outcome of any of Dr. King's analyses would be if done differently, i.e., no alternative hypothesis and no test for accuracy. As such, it is merely criticism, not an expert opinion and not impeachment evidence. Expert opinions to impeach a witness are limited to truthfulness or untruthfulness, Rule 608 (a).

Dr. Grabowski also does not find any error in Dr. King's foundational facts or statistics. *See, e.g., Petree v. Victor Fluid Power, Inc*., 887 F. 2d 34 (3d Cir. 1984); *Kennemur v. California*, 133 Cal. App. 2d 907 (Cal. App. 1982). Dr. Grabowski did not himself observe any particular foundational facts about the off-label marketing of Neurontin or of the prescriptions

written during or as a consequence of the defendant's off-label promotion. Accordingly, his opinion impeachment does not come within Rule 608(b).

Accordingly, his testimony is excluded by Rules 608 and 403.

4. Dr. Grabowski's opinions merely recite and parrot other Defendants' experts and do not rest on his own analysis or investigation.

His opinion is that he is right because hired Defendants' experts Dr. Donofrio, Dr. Bird, Dr. Slaby, Dr. Potolicchio, and Dr. Brenner are right and he adopts their personal opinions. *See* Grabowski report, page 10, paragraph 21; paragraphs 23-29. Accordingly, they violate Rule 703. *See, e.g.***,** *Dura Automotive Systems of Indiana, Inc. v. CTS Corp.*, 285 F.3d 609, 613 (7th Cir. 2002); *TK-7 Corp. v. Estate of Barbouti*, 993 F.2d 722, 731-34 (10th Cir. 1993).

For the foregoing reasons, Plaintiff objects to Dr. Grabowski's proposed testimony in its entirety and assert that it is not relevant, Rule 401, is not the proper subject of expert testimony, Rules 702-704, is more prejudicial and confusing than helpful, Rule 403, is not proper impeachment, Rule 608, and does not have a reliable foundation, Rule 703.

Page: Line	***Statement***	***Objection***
2:21--3:4 and	"As an initial matter, it is important to keep in mind that Dr. King is not offering the opinion that Mr. Smith's particular Neurontin prescription was caused by allegedly improper off-label promotion. Dr. King has done no analysis specific to Mr. Smith or anyone else who has taken Neurontin. Dr. King was not familiar with the facts of Mr. Smith's case at the time he was deposed in this litigation. In short, Dr. King has not attempted to provide valid economic evidence linking the specific prescription of Neurontin given to Mr. Smith to any alleged misrepresentation by defendants."	Improper opinion on how to weigh evidence, legal opinion on admissibility and relevance, beyond scope of permissible expert testimony, not helpful to jury, improper impeachment; not relevant, conclusory, argumentative. FRE 401,403, 608, 702; 704.
First Demons-trative	**<u>Summary of Opinions</u>** - Dr. King has provided no valid economic basis to conclude that off-label marketing of Neurontin indirectly influenced all, or substantially all, physicians prescribing Neurontin. - Dr. King's analysis does not prove that	Not relevant, legal opinion, conclusory opinion, mere criticism. Not relevant, legal opinion, conclusory

	any specific Neurontin prescription was caused by any alleged misrepresentation by defendants. -Dr. King admittedly has not done an analysis specific to Mr. Smith and the Facts of this case. -Dr. King's opinions regarding the effect of off-label promotion of drugs generally and Neurontin specifically are flawed and unsupported.	opinion, mere criticism. Not relevant, legal opinion, argumentative, conclusory opinion, mere criticism. Not relevant, legal opinion, argumentative, conclusory opinion, mere criticism.
3:5-7	Dr. King has not offered an economic basis for his conclusions in this case that increases in Neurontin prescriptions for various off-label indications are attributable to allegedly improper promotion.	Not relevant, legal opinion, argumentative, conclusory opinion, mere criticism.
3:20-21	Dr. King simply assumes that (a) the sales calls were all fraudulent; and (b) the sales calls caused substantially all the prescriptions written by this group of psychiatrists.	No foundation, Improper opinion on how to weigh evidence, legal opinion on admissibility and relevance, beyond scope of permissible expert testimony, not helpful to jury, improper impeachment; not relevant, conclusory, argumentative. FRE 401,403, 608, 702; 704.
3:23--4:1	Dr. King's assumption has no economic or statistical validity.	Subjective, argumentative, and untestable opinion; improper opinion on how to weigh evidence, legal opinion on admissibility and relevance, beyond scope of permissible expert testimony, not helpful to jury, improper impeachment, not relevant, conclusory, argumentative. FRE 401,403, 608, 702; 704.
4:2-4	Dr. King has done no analysis of the extent of correlation shown in Plaintiff's counsel's chart and he overlooks important differences in the patterns shown of promotion and prescriptions	There is no 'Plaintiffs counsel's chart.' This is merely defense argument clothed as expert testimony. Mere criticism, beyond scope of permissible expert testimony, not helpful to jury, improper impeachment, not relevant, conclusory, argumentative. FRE 401, 403, 608, 702; 704.
4:4-5	Second and more fundamentally, even if a correlation existed, it would not prove causation.	Legal opinion, argumentative, beyond scope of permissible expert testimony, not helpful to jury, improper

		impeachment, not relevant, conclusory, argumentative. FRE 401,403, 608, 702; 704.
4:12-15 4:18-19	Dr. King's causal assertion is contrary to standard economic practice that attempts to measure the casual impact of one factor (in this case the allegedly improper promotion) on an outcome variable (in this case Neurontin's off-label usage) by isolating the effect of that one factor from the effect of other factors that influence that outcome variable. Dr. King has not addressed any of the various factors that may have affected off-label use of Neurontin.	Subjective untestable opinion, argumentative, beyond scope of permissible expert testimony, not helpful to jury, improper impeachment, not relevant, conclusory, argumentative. FRE 401,403, 608, 702; 704.
2d Demons-trative 4:21-23	**Off-Label Prescribing:** • Off label prescribing by physicians is a common, accepted clinical practice • Physicians often conclude that an off-label treatment is in best interests of patient • Physicians need to treat patients for conditions where there is no FDA- approved drug or few treatment options • New medical discoveries outpace FDA approval process A review of the literature and expert reports in these cases reveal uniform consensus that there are numerous factors unrelated to allegedly improper promotion that can affect off-label prescribing.	Beyond scope of his expertise, not qualified, no foundation, opinion is an unfounded parroting of other defense expert witness contentions in violation of Rule 704. Subjective untestable opinion, argumentative, beyond scope of permissible expert testimony, not helpful to jury, improper impeachment, not relevant, conclusory, argumentative. FRE 401,403, 702; 704.
5:6-8	Dr. King, however, has not addressed or even acknowledged any factor other than alleged improper promotion, much less attempted to control for them.	Subjective untestable opinion, argumentative, beyond scope of permissible expert testimony, not helpful to jury, improper impeachment Not relevant, conclusory, argumentative. FRE 401,403, 608, 702; 704.
5:20-21	Indeed, the off-label use of a drug for a particular indication is frequently	Beyond scope of his expertise, not qualified, no foundation, opinion is an

	endorsed in medical reference guides long before the drug receives FDA approval.	unfounded parroting of other defense expert witness contentions in violation of Rule 704; Not relevant, conclusory, argumentative. FRE 401,403, 608, 702; 704.
5:22-23	The available FDA- approved medications do not provide adequate treatment for a large number of patients.	Beyond scope of his expertise, not qualified, no foundation, opinion is an unfounded parroting of other defense expert witness contentions in violation of Rule 704.
6:4-7 **Third Demons-trative**	Off label prescribing is particularly common among anti-epileptic drugs ("AED's"), including Neurontin. Therefore, it cannot simply be presumed that high off-label usage levels or sharp increases in off-label use are the result of improper promotion. **<u>Factors Influencing Off-Label Prescribing:</u>** Patient-specific factors - Contraindications - Side effect profile - Response to other treatments Physician- Specific factors - Positive experience with drug or similar drugs for off-label use from many sources Neurontin-specific factors -Lack of drug-drug interactions and contraindications -Demonstrated efficacy for off-label uses - 2002 approved for treating PHN, a type of neuropathic pain	Beyond scope of his expertise, not qualified, no foundation, opinion is an unfounded parroting of other defense expert witness contentions in violation of Rule 704 Beyond scope of his expertise, not qualified, no foundation, opinion is an unfounded parroting of other defense expert witness contentions in violation of Rule 704; Subjective untestable opinion, argumentative, not helpful to jury, conclusory, argumentative. FRE 401,403, 702, 703, 704.
7:9-12	In fact, Dr. King himself concedes that prescription medications are experience goods. If patients and physicians did not experience positive results with Neurontin, patients would not have continued to use it and physicians would not have continued to prescribe it.	Beyond scope of his expertise, not qualified, no foundation, opinion is an unfounded parroting of other defense expert witness contentions in violation of Rule 704; subjective untestable opinion, argumentative, not helpful to jury, conclusory, argumentative. FRE 401, 403, 702, 703, 704; improper impeachment, FRE 608.
7:15-21	It is likely that numerous factors would	Subjective untestable opinion,

	have led to significant off-label prescribing of Neurontin wholly apart from any alleged improper promotion, including: the prevalence of off-label prescribing in general; the characteristics of Neurontin that make it an obvious candidate for off-label prescribing; physicians' positive experiences with Neurontin and other AEDs in treating the relevant conditions; and the numerous developments over time pertaining to Neurontin that likely underscored Neurontin's utility in treating a variety of off-label conditions and contributing to such uses.	argumentative, not helpful to jury, conclusory, argumentative. FRE 401, 403, 702, 703, 704. Beyond his expertise, no foundation. FRE 702, 703, 704.
7:22--8:2 8:6	As confirmed by several of the medical experts who have submitted reports in this litigation, Neurontin is a good candidate for off-label use because of its lack of drug-drug interactions, contraindications, and demonstrated efficacy for off-label conditions with few alternative treatment options. Neurontin, however has a limited potential for drug interactions.	Beyond scope of his expertise, not qualified, no foundation, opinion is an unfounded parroting of other defense expert witness contentions in violation of Rule 702-704.
8:11-12	Dr. King's report fails to assess and quantify the effect of any of these developments or other factors on Neurontin's off-Label usage	Improper opinion on how to weigh evidence, legal opinion on admissibility and relevance, beyond scope of permissible expert testimony, not helpful to jury, improper impeachment; not relevant, conclusory, argumentative. FRE 401, 403, 608, 702; 704.
9:4 **Fourth Demons-trative**	Finally, Dr. King's report from numerous flaws limitations. **<u>Flaws in Dr. Kings Analysis:</u>** • Dr. King has not performed a valid causation analysis - Correlation vs. Causation • Dr. King's reliance on general	Improper opinion on how to weigh evidence, legal opinion on admissibility and relevance, beyond scope of permissible expert testimony, not helpful to jury, improper impeachment, not relevant, conclusory, argumentative. FRE 401, 403, 608, 702; 704. Improper opinion on how to weigh evidence, legal opinion on admissibility and relevance, beyond scope of permissible expert testimony, not

	pharmaceutical literature is misplaced and doesn't support specific conclusions about Neurontin • Claim that effects of off-label marketing of Neurontin would continue virtually unabated after promotion is terminated is unsupported • Dr. King's claim about Defendants' marketing expenditures vs. costs of research and development is flawed	helpful to jury, improper impeachment, not relevant, conclusory, argumentative. FRE 401, 403, 608, 702; 704.
9:6-14	Dr. King has offered no valid economic or statistical basis for concluding that any particular Neurontin prescriptions were caused by any particular alleged misrepresentation by defendants. He has done no case-specific analysis pertaining to Mr. Smith and he has no case- specific conclusions. More generally, Dr. King conceded that he has not done any causation analysis specific to Neurontin. He has performed no analysis of the causes of the trends he observes in his data. In particular, Dr. King has done nothing to account for the numerous other causes of prescriptions besides promotion, including doctors' and patients' experiences, even though he conceded that drugs are experience goods.	Subjective untestable opinion, argumentative, no foundation, not helpful to jury, conclusory, argumentative. FRE 401, 403, 702, 703, 704.
9:17-20	This "correlation" is questionable. Off-label prescribing by these psychiatrists was on the rise before any detailing started and continued long after detailing stopped. In any event, even if correlation existed, it would not prove causation, for the reasons I already discussed.	Improper opinion on how to weigh evidence, legal opinion on admissibility and relevance, beyond scope of permissible expert testimony, not helpful to jury, improper impeachment, not relevant, conclusory, argumentative. FRE 401, 403, 608, 702; 704.
9:22--10:2	None of the literature he cited offers any Neurontin- specific analysis of the impacts of promotion, and it is not valid	Subjective untestable opinion, argumentative, no foundation, not helpful to jury, conclusory,

	for Dr. King to generalize that literature to this case. 10:4-9 None of the literature relates to alleged fraudulent promotion. Any false or misleading messages about a prescription drug would be unlikely to have long-lived effect because they will be revealed as inaccurate as physicians and patients learn about the drug from their own experience. The fact that Neurontin sales have increased steadily over time, even in the face of allegations of improper marketing, suggest that positive experiences with Neurontin are a key factor driving sales.	argumentative. FRE 401, 403, 702, 703, 704.
10:10-12	Second, even if literature regarding the impact of truthful pharmaceutical promotion were relevant and could be applied to this case, it would not support Dr. King's conclusion that Neurontin promotion had a substantial impact on more prescribing of Neurontin.	Subjective untestable opinion, argumentative, no foundation, not helpful to jury, conclusory, argumentative, FRE 401,403, 702, 703, 704, improper opinion on how to weigh evidence, legal opinion on admissibility and relevance, beyond scope of permissible expert testimony, not helpful to jury, improper impeachment; irrelevant.
10:15-16 11:3-6	There is also no basis in the literature for Dr. King's assertion that effects of marketing and promotional stocks are long lived. Hence the consensus of the economic research on this issue does not support Dr. King's claim that the effects of off-label marketing would continue virtually unabated into the future, even after such promotion is terminated.	Subjective untestable opinion, argumentative, no foundation, not helpful to jury, conclusory, argumentative. FRE 401,403, 702, 703, 704. Improper opinion on how to weigh evidence, legal opinion on admissibility and relevance, beyond scope of permissible expert testimony, not helpful to jury, improper impeachment; irrelevant, conclusory, argumentative.
11:7-11	Dr. King also does not provide any valid basis for this conclusion that suppression of information about serious adverse affects enabled the growth in off-label sales of Neurontin. A product's side effect profile cannot be evaluated in isolation of other factors; rather it must be evaluated in terms of a products	Subjective untestable opinion, argumentative, no foundation, not helpful to jury, conclusory, argumentative. FRE 401,403, 702, 703, 704; Improper opinion on how to weigh evidence, legal opinion on admissibility and relevance, beyond scope of permissible expert testimony, not

	overall clinical benefits and risks and in comparison to what other therapeutic alternatives exist to treat a particular condition.	helpful to jury, improper impeachment; not relevant.
11:16-22	As discussed by Dr. Donofrio and others, the circumstances surrounding Neurontin off-label prescribing are very different from those surrounding the prescribing of SSRIs for depression or H2 blockers for ulcers. In particular, patients with neuropathic and chronic pain are generally faced with limited therapeutic options and are often found to be non-responsive to many of the available responsive therapies with do exist. Hence it is inappropriate for Dr. King to generalize from experiences with these other drugs to the circumstances surrounding the off-label use of Neurontin at issue in this case.	Beyond scope of his expertise, not qualified, no foundation, opinion is an unfounded parroting of other defense expert witness contentions in violation of Rule 702-704. Improper opinion on how to weigh evidence, legal opinion on admissibility and relevance, beyond scope of permissible expert testimony, not helpful to jury, improper impeachment; not relevant. FRE 401, 403, 608.
12:2	Dr. King's analysis of this issue exhibits a number of flaws.	Argumentative, improper opinion on how to weigh evidence, legal opinion on admissibility and relevance, beyond scope of permissible expert testimony, not helpful to jury, improper impeachment; not relevant. FRE 401, 403, 608.
12:5-9	This is misleading on two accounts—First, the typical pharmaceutical company product mix is diversified across many business lines which as over-the-counter drug products, consumer products, and animal products, which involve less research intensive products than prescription drugs. Second, as its category name indicates, SG&A expenses encompass much more than promotional expenses for prescription pharmaceuticals.	Subjective untestable opinion, argumentative, no foundation, not helpful to jury, conclusory, argumentative. FRE 401,403, 702, 703, 704.
12:21-23	Hence a careful analysis of the economic literature on this topic does not support Dr. King's allegation that marketing intensities exceed R&D	Improper opinion on how to weigh evidence, legal opinion on admissibility and relevance, beyond scope of permissible expert testimony, not

	intensities in prescription pharmaceuticals.	helpful to jury, improper impeachment; not relevant. FRE 401, 403, 608.
13:1-8	In summary, Dr. King has offered no opinions specific to Mr. Smith and this case, including whether Mr. Smith's Neurontin prescription was attributable to allegedly improper promotion of Neurontin. Nor has he provided an economic basis for the opinions he seeks to offer into his case regarding Neurontin and off-label prescribing patterns by doctors. His analysis is flawed for the reason I have discussed and does not establish that Mr. Smith's doctors prescribed Neurontin to him because of any alleged misrepresentations by defendants. My opinions are expressed to a reasonable degree of scientific certainty, and are based on my review of materials in this litigation as well as my education, training and experience as an economist.	Argumentative, improper opinion on how to weigh evidence, legal opinion on admissibility and relevance, beyond scope of permissible expert testimony, not helpful to jury, improper impeachment; not relevant. FRE 401, 403, 608, 702-704

6. <u>Janet Arrowsmith-Lowe, M.D.</u>

Page: Line	***Statement***	***Objection***
3:13	The Neurontin labeling was adequate under the regulations and provided appropriate information for safe and effective use.	Cumulative with the opinions of Dr. Ruggieri.
3:18	There was no reason for Pfizer to warm of suicidal behavior in the Neurontin labeling prior to the requirement of class labeling in 2009 as the available information did not establish that this	Cumulative with the opinions of Dr. Ruggieri

	medicine was associated with an increased risk of suicidal behavior.	
9:19	Based upon my review of the company's postmarketing pharmacovigilance practices, including information provided by Pfizer to FDA after 2004, there was no evidence of a signal for suicide at any time following approval of the NDA in December of 1993.	Cumulative with the opinions of Dr. Ruggieri. Lack of Foundation. Defendants failed to produce documents from the safety surveillance activities during the Parke-Davis era other than periodic reports. Dr. Ruggieri has no way to know of the safety activities within the company during the Parke-Davis era.
10:5	Because of their increased risk for suicide, clinicians expect these types of patients will have a higher suicide rate than the general population and that suicides can be expected in any clinical trial enrolling such patients regardless of treatments they may receive.	Rules 702-704. Dr. Arrowsmith employs no reliable methodology to conclude that suicides can be expected in "any" clinical trial of these types of patients. She fails to consider trials that have too few patients to observe these effects and ignores Pfizer's own evidence that shows that most trials did not in fact have a completed suicide. Lack of foundation. Dr. Arrowsmith speculates as to what clinicians can expect concerning suicide, yet provides no basis for such a statement.
12:10	Uncontrolled trials may help establish the potential beneficial effects of a new drug.	Lack of foundation. FDA regulations do not allow such trials to establish benefits. Prejudice outweighs probative value.
14:9	It is my opinion, and Dr. Blume agrees, that this difference in the incidence of depression, although numerically different, is not statistically or clinically different and does not demonstrate an	Lack of foundation. Dr. Blume does not agree with this statement.

	increased risk for depression with patients assigned to Neurontin.	
14:13	Had FDA reviewers concluded that Neurontin increased the risk of depression or suicide, they would have been obligated to have required a warning in the label at the time the drug was approved.	Lack of foundation, Speculation, Likely to confuse the jury, Prejudice outweighs the probative value. The witness can not speak to what the FDA would have had to do with such information. Furthermore, the jury could be mislead into believing that the absence of a warning is tantamount to the FDA dismissing the need for one.
15:3	Dr. McCormick did not conclude that the clinical trial data demonstrated an increased risk for depression or suicidal behavior among the Neurontin treated patients.	Lack of foundation, Misleads the jury, Prejudice outweighs probative value. Dr. McCormick stated on page 117 of exhibit 7563: "**[l]ess common but more serious events may limit the drug's widespread usefulness…. [D]epression, while it may [not be] an infrequent occurrence in the epileptic population, may become worse and require intervention or lead to suicide, as it has resulted in some suicide attempts.**" Dr. Arrowsmith-Lowe can not speak as to what Dr. McCormick did not conclude. Furthermore, Dr. Arrowsmith-Lowe's testimony is inconsistent with the document she cites.
15:16	Based on the regulatory record, it is clear that Dr. McCormick continued to evaluate the safety evidence from the company's submissions in 1993 and again in 2002 and found no basis to conclude that Neurontin was associated with an increased risk of suicidal behavior or depression.	Lack of foundation, Misleads the jury, Prejudice outweighs probative value. Dr. McCormick stated on page 117 of exhibit 7563: "**[l]ess common but more serious events may limit the drug's widespread usefulness…. [D]epression, while it may [not be] an infrequent occurrence in the epileptic population, may become worse and**

		require intervention or lead to suicide, as it has resulted in some suicide attempts." Dr. Arrowsmith can not speak as to what Dr. McCormick did not conclude. Furthermore, Dr. Arrowsmith-Lowe's testimony is inconsistent with the document she cites.
16:5	Dr. McCormick evaluated the full spectrum of adverse events, including episodes of depression and suicidal behavior, before concluding that Neurontin was safe and effective and should be approved for marketing.	Lack of foundation, Misleads the jury Dr. McCormick stated that "In Conclusion, NDA 20-235 is approvable with appropriate labeling in a specific population. Specifically labeling should reflect that while short term efficacy has been demonstrated as add-on treatment in the refractory partial epilepsy population, the firm has not demonstrated that this effect is sustained." Dr. Arrowsmith-Lowe's statement is incomplete at best and will mislead the jury into believing that Dr. McCormick concluded the drug was safe and effective for purposes other than epilepsy.
21:11	In December 2005, Pfizer agreed to update the Neurontin package insert by replacing the terms "suicidal" and "suicide gesture" with the terms "suicide attempt" and "suicide". These changes are reflected in **Exhibit 7026,** which is the December 2005 Neurontin label. FDA considered these changes to be "minor," as you can see in the current slide. **[SHOW POWERPOINT HERE (FDA'S 2005 'MINOR' CHANGE TO SUICIDE-RELATED ADVERSE EVENT TERMS IN NEURONTIN'S LABELING)]** This is the November 22, 2005 email from FDA requesting the labeling change, which is **Exhibit 7204.** The original terms "suicidal" and "suicide gesture" had been approved by	Cumulative with Dr. Ruggieri 23:5

	FDA based on a modification of the standard adverse event coding dictionary used both by FDA and pharmaceutical companies marketing drugs in the U.S. The Neurontin labels containing these terms were adequate for the purpose of putting prescribers on notice about potentially "suicidal" adverse events reported from the clinical trials. In 2005, this minor labeling change updated the clinical adverse event terminology in the Neurontin label, but did not change the label in any significant way. These changes in terminology are analogous to an old way of referring to persons with epilepsy as having "fits" or "epileptic fits" instead of the more current terminology "seizures" or "epileptic seizures". The older or archaic terminology is "epileptic fit" and the newer term is "epileptic seizure". These terms basically have the same meaning to a clinician; it is just that the term "seizure" is the currently preferred terminology. The changes in labeling terminology for Neurontin are similar to the changes in the way we refer to the clinical manifestations of epilepsy.	
22:17	One example of the FDA's perspective on the use of clinical trials data for this type of analysis is **Exhibit** 7209, which is an April 12,2005 letter from Dr. Katz of the FDA to Andrew Finkelstein of the Finkelstein Law Firm. Prior to this letter, the Finkelstein firm had been submitting adverse event reports to FDA that they claimed involved Neurontin and suicidal behavior. FDA makes it clear that uncontrolled adverse event data on suicide are not useful in evaluating whether Neurontin was associated with an increased risk for suicidal behavior. Specifically, as you can see in this slide **[SHOW POWERPOINT HERE** (FDA:	Cumulative with Dr. Weiss-Smith 16:1 Lack of Foundation The document does not state that the uncontrolled adverse event data are not useful in evaluating whether Neurontin was associated with an increased risk. Prejudice outweighs probative value.

	CONTROLLED TRIALS ARE ONLY WAY TO ASSESS WHETHER NEURONTIN IS ASSOCIATED WITH INCREASED RISK OF SUICIDE)], in 2005 FDA told lawyers in the Finkelstein fIrm that "these illnesses are well-known to be associated with an increased risk of suicide compared to the general population. Further, in the absence of an appropriate control group, it will be difficult, if not impossible, to assess the role of any other factors that might explain these events, such as concomitant medications."	
23:6	This statement by FDA supports one of my major objections to Dr. Blume's opinion - although FDA advised the plaintiffs' lawyers that uncontrolled data was not appropriate to analyze suicidal behavior, her report spends dozens of pages relying upon uncontrolled data.	Lack of foundation, Misleading, Prejudice outweighs probative value. FDA never stated it was inappropriate to analyze the uncontrolled data. FDA stated that it was difficult to assess the role of Neurontin. Dr. Blume's opinions look to the data as to whether there was a signal and an association- neither of which establish a causal relationship. Dr. Blume also opined that the uncontrolled data supports a causal conclusion based upon other factors- an opinion which has been tested under Daubert and which was specifically allowed by the MDL Court.
23:10	FDA has also commented specifically on the use of spontaneous adverse event data to analyze suicidality. In an April 1, 2008 email to Dr. Alex Ruggieri, which is labeled Exhibit 7392 and shown on this slide, [SHOW POWERPOINT HERE (FDA: CONTROLLED TRIAL DATA ARE THE ONLY WAY TO ESTABLISH WHETHER AEDS ARE RESPONSIBLE FOR SUICIDE)], FDA stated: Concerning your question why data from the FDA Adverse Event Reporting System (AERS) has not been analyzed or made public, the agency does not believe that spontaneous post-	Lack of Foundation Document was purportedly sent to Dr. Ruggieri, but Plaintiffs have challenged the authenticity. Please see objection to Dr. Ruggieri 20:17 which is adopted here by reference. Cumulative with Dr. Ruggieri 20:17

	marketing reports can be interpreted appropriately in this situation. Patients taking these drugs have a high background rate of suicidal thoughts/behaviors, and it is not possible to tell from AERS reports, whether the drug caused them. In the agency's view, the only way to establish whether or not the drugs are responsible for suicidality is to analyze controlled trial data.	
23:22	FDA commented on the use of spontaneous adverse event data to assess suicidality associated with Neurontin for a third time at the July 10, 2008 Joint Meeting of the Peripheral and Central Nervous System and Psychopharmacologic Drugs Advisory committees. A transcript of this meeting is labeled Exhibit 7257. At this Joint Advisory Committee Meeting, as shown in the current slide [SHOW POWERPOINT HERE (FDA: USE PLACEBO- **CONTROLLED TRIALS BECAUSE POSTMARKETING DATA** ARE **UNINTERPRETABLE)],** Dr. Russell Katz of FDA stated, " ... we had long ago decided that postmarketing data are not the right data to look at, or we don't believe that these sorts of things where there is a high background rate of suicidality so defined in these populations, I think that we have concluded that postmarketing data is uninterpretable, and that is why we went to placebo-controlled trials."	
24:7	Getting back to the June 2006 submission, this analysis included 8829 patients, in which 336 cases of "possibly suicide-related" adverse events were identified. Further review of the 336 possible cases suicide-related adverse events associated with Neurontin use revealed zero actual cases of completed suicide, zero cases of attempted suicide, and zero cases of "preparatory acts towards imminent suicidal behavior" in the data set. The incidence of suicidal ideation which is	Cumulative with Dr. Ruggieri 22:6

	another term for suicidal thinking among Neurontin users was nearly identical to that of placebo patients, specifically 3.9 per 10,000 in Neurontin patients and 3.7 per 10,000 in placebo patients. **[SHOW POWERPOINT HERE (CONTROLLED TRIALS: NO INCREASED RISK OF SUICIDE WITH NEURONTIN)]** Pfizer wrote, "[1]he currently submitted data provides further support for the conclusion that Neurontin neither causes nor is associated with an increased risk of suicidal behavior and thinking, including completed suicide, suicide attempt, suicide gesture and suicide ideation." Thus, these data do not demonstrate an increased risk for suicide or suicidal behavior in patients treated with Neurontin as compared to patients treated with placebo.	
24:21	As you can see depicted in the slide currently being shown **[SHOW POWERPOINT (EVALUATIONS OF DEPRESSION AND SUICIDALITY)],** after numerous evaluations of data on depression and suicidality, neither FDA nor the Company detected a signal for increased depression or suicidality based on Neurontin data alone.	Lack of foundation. Dr. Arrowsmith can not speculate on what the FDA detected.
25:3	Following the company's submission of the controlled clinical trial data in 2006, FDA included the Neurontin clinical trial data on suicidality in its own analysis, along with controlled clinical trial data for 10 other antiepileptic drugs, or AEDs. This 2008 FDA analysis is labeled Exhibit 7559. FDA concluded that all AEDs, including those not represented in this analysis, and including drugs not yet approved as AEDs, will be required to put suicide-related warnings in their labels. The FDA analysis was not designed to establish whether any particular AED, including Neurontin, is associated with an increased risk for suicide, but rather	Cumulative Generally with Dr. Gibbons.

	is the AED class of drugs associated with an increased risk for suicide. The question concerning whether there was an increased risk for each individual AED was raised during the July 2008 Joint Advisory Committee meeting. The FDA statistician, Dr. Levenson, confirmed that the combined analysis demonstrating an increased risk for suicide required the entire data set from all 11 AEDs which you can see on the slide that is currently being shown. [SHOW POWERPOINT HERE (FDA META-ANALYSIS - ENTIRE DATA NECESSARY TO DRAW CONCLUSIONS)] Dr. Twyman, a member of the advisory committee, asked: "Let's assume that the effect is generalizable to the class of AEDs. But if you look at the compounds individually, could one draw the conclusion individually that compounds have a risk, or do you need to the entire data set of all the AEDs put together in order to draw the conclusion that AEDs have a signal?" Dr. Levenson, an FDA statistician, replied: "I would say we need the entire data set in this case."	
26:8	FDA has not concluded that AEDs cause suicide or suicidal behavior. In Exhibit 7558, a December 2008 alert on suicidal behavior, suicidal ideation and antiepileptic drugs, shown in the current slide, [SHOW POWERPOINT HERE (DECEMBER 16, 2008 - FDA TO PHYSICIANS: FDA HAS NOT CONCLUDED AEDS CAUSE SUICIDAL BERA VIORS] FDA stated that its analysis does not mean that it has concluded that there is a causal relationship between AEDs and suicidal behavior, and that FDA is not advising physicians or patients to discontinue appropriate prescribing of AEDs.	Cumulative with Dr. Gibbons 5:9 Lack of Foundation. The quote from the 12/2008 FDA alert is "Posting this information does not mean that FDA has concluded there is a causal relationship between the drug products and the emerging safety issue." This does not state that the FDA has concluded that there is no causal link. It makes no statement as to the absence or presence of the link. Rule 702. Dr. Arrowsmith-Lowe uses faulty methodology when she ignores, within

		the same document the statement: "FDA's pooled analysis of 199 clinical trials ... showed that patients randomized to receive one of the anti-epileptic drugs had almost twice the risk of suicidal behavior (0.43%) compared to patients randomized to receive placebo (0.24%)"
27:21	It is my opinion that FDA would not have removed this language if FDA scientists and clinicians believed it had any relevance to the safe or effective use of the product. I believe Dr. Blume is mistaken in her assertion that Neurontin's possible effects on neurotransmitters in the central nervous system has any bearing on the safety of Neurontin, an opinion that is supported by FDA's deletion of this language from the Neurontin labels.	Lack of foundation Dr. Arrowsmith-Lowe speculates on what the FDA would do. Rules 702-704 Dr. Arrowsmith-Lowe is not a pharmacologist and lacks the expertise to contradict Dr. Blume's testimony. Furthermore, Dr. Arrowsmith does not express this opinion to a reasonable degree of scientific certainty; she simply states she "believes" this is true.
30:13	Dr. Blume's report sets forth a purported "Proportional Reporting Rate" ("PRR") of the FDA AERS database in support of her contention that the postmarketing surveillance data revealed a "signal" for suicide. The analysis presented in Dr. Blume's report is not a PRR. Rather, Dr. Blume merely presents the percentage of suicide events for each drug relative to the total number of adverse events for that drug. This is not the generally accepted method for calculating a PRR, which would require an analysis of the entire AERS database. Even if her analysis were a generally accepted-type of PRR, Dr, Blume has not followed generally accepted methodology in interpreting the information. As stated by Dr. Brian Strom (who Dr. Blume has acknowledged as an authority in the field of pharmacoepidemiology) in a 2005 article that is labeled **Exhibit 987,** " ... true signals should emerge from clinical judgment and that statistical	Cumulative with Dr. Weiss-Smith 10:9.

	algorithms, such as PRRs, should be used as supplements to clinical and epidemiological judgment, not replacements." PRRs and the adverse event reports used to calculate them are hypothesis-generating only. Spontaneous adverse event reports are voluntary reports of possible adverse effects of medications submitted to FDA or the manufacturer by healthcare providers, patients, and other interested parties. These reports are often subjective and generally are only useful in generating signals of possible new safety information,	
31:6	Dr. Blume is not qualified to assess clinical adverse event data in a meaningful way. She is neither a clinician nor an epidemiologist and does not have the appropriate qualifications to interpret clinical or epidemiological data in evaluating her purported PRR results.	Prejudice outweighs probative value, Relevance The MDL court has already ruled that Dr. Blume does possess this expertise.
31:9	Dr. Blume further asserts in her declaration that by the fourth quarter of 2002, increases in reports of serious adverse events were due to increases in off-label use. As she acknowledged in her first deposition, notoriety bias during this time period would likely increase reporting rates of adverse events.	Lack of foundation Dr. Blume states that the notoriety occurs after June 2003. Dr. Arrowsmith-Lowe misstates Dr. Blume's testimony.
32:8	Third, the various tables setting forth clinical trial withdrawals are incomplete and, when appropriately configured, do not demonstrate any consistent pattern signaling a risk of suicide or suicidality among Neurontin users.	This opinion has never been disclosed under Rule 26 nor has any charts created by Dr. Arrowsmith-Lowe ever been disclosed. Lack of foundation
32:16 Also 32:21--35:3	I also have an opinion on advertising for medicines as it relates to this case. I have expertise in this area. I have experience in providing information to the public on approved and unapproved medications through my work in the Office of AIDS and Special Health Concerns and am very familiar with the regulations addressing labeling,	Rules 702-704. Dr. Arrowsmith-Lowe does not possess the expertise she claims. Her claims of experience providing information to the public while working in the Office of AIDS has nothing to do with pharmaceutical marketing regulations.

	advertising and promotion of prescription medicines. [32:21-35:3] not reproduced for brevity.	As to her experience with marketing issues, her testimony makes clear she lacks the requisite expertise: Q. Okay. Did you ever work directly in DDMAC? A. No, I was not employed in DDMAC. Q. Did you ever write any letters on behalf of DDMAC to be sent out to a pharmaceutical company? A. No, I did not. Q. Okay. In your regulatory consulting experience, did you ever respond to a DDMAC letter? A. No, I have not. Q. Okay. Have you ever been -- have you ever been asked to provide -- consulted on marketing issues in your regulatory consulting activities? A. Can you explain what you mean by that. Q. I think we said last time some of your activities related to litigation and some of your activities related to regulatory consulting to pharmaceutical companies; is that correct? MR. BARNES: Objection, misstates her prior testimony. If you understand the question, please answer it. THE WITNESS: Well, I've provided regulatory consulting for device manufacturers, biological manufacturers, OTC manufacturers. BY MR. ALTMAN: Q. Okay. A. In addition to pharmaceutical prescription drug manufacturers. Q. Okay. And in those consulting activities, outside of the context of litigation, so we're not talking about litigation, have you ever provided any consulting in terms of marketing issues? A. In -- by marketing, what exactly do you mean by marketing? Q. Has anybody ever asked you whether a marketing piece they would like to use complies with the regulations? A. No, I have not been asked to review marketing pieces in that way. Q. Have you ever been asked to review a letter from DDMAC that one of the -- your consulting clients has received? A. Not from DDMAC, no. Q. How about from the FDA in terms of any marketing issues? A. I've been asked to review, yes, letters from FDA more addressing safety issues. Q. Okay. Have you ever been asked to review any regarding marketing issues? A. Strictly speaking marketing, probably not, not that I recall. Q. When you were at the FDA, you said you worked closely with DDMAC? A. That's correct. Q. And what did you do with the people from DDMAC? A. Well, I was -- I reviewed a paper by Lou Morris who was -- at the time was head of DDMAC to -- I'm trying to remember what -- I don't remember. It was one of the products that I was involved with early on in my career at FDA. And he had drafted a -- an article addressing some marketing issues about that product. And I can't remember whether it was aspirin or acetaminophen. But I was asked to -- he asked me to review the paper. And so I reviewed and commented on the paper.

		And certainly I was aware of DDMAC activities and how the label, approved product label was used to compare marketing promotional materials with the current product label. Q. Aside from that particular project, were there any other projects in which you worked with DDMAC? A. I don't remember any specific ones, but I certainly worked with other DDMAC employees. Q. Did anybody from DDMAC ever -- and maybe I asked this. Ever ask you please review these materials here and tell us whether this complies with our regulations? A. I don't remember. Q. If you did it, would you remember? MR. BARNES: Objection. THE WITNESS: I -- I might. I don't -- you know, I was in the postmarket group at -- and that's where I think most of those interactions took place, is when I was in the postmarket group at CDER. I don't know. I responded to a lot of consultations. I don't remember specifically consultation from DDMAC, though.
Slide 18	Entire Slide	*See* 23:10

7.

Robert Gibbons, Ph.D.

Page: Line	***Statement***	***Objection***
3:21	Fourth, there is no basis for a suicide warning specific to gabapentin because there is no signal of increased risk.	Rule 702. Dr. Gibbons has no experience in the interpretation of clinical signals. His statement exceeds the scope of his expertise. Dr. Gibbons' opinion is cumulative of Defendants' other general causation expert opinions (e.g., Ruggieri, Arrowsmith-Lowe, Weiss-Smith).
5:9	The FDA has indicated that the meta-analyses, such as this one, do not indicate a causal link between these drugs and suicidality. [SHOW DEMONSTRATIVE: 1212008 ALERT].	Cumulative with Dr. Arrowsmith-Lowe 26:8. Lack of Foundation. The quote from the 12/2008 FDA alert is "Posting this information does not mean that FDA has concluded there is a causal relationship between the drug products and the emerging safety issue." This does not state that the FDA has concluded that there is no causal link. It makes no statement as to the absence or presence of the link. Rule 702. Dr. Gibbons uses faulty methodology when he ignores, within the same document the statement: "FDA's pooled analysis of 199 clinical trials ... showed that patients randomized to receive one of the anti-epileptic drugs had almost twice the risk of suicidal behavior (0.43%) compared to patients randomized to receive placebo (0.24%)"
5:15	If these two drugs were not a part of the study, there would be no Alert.	Lack of foundation. Speculates as to what the FDA would have done.

6:2	In fact, FDA's analysis shows that there is no increased risk in North Americans, or psychiatric patients, or non-hospitalized patients, or women.	Rule 702. Dr. Gibbons' statement does not comport with generally accepted practices. Although the results for these groups are not statistically significant, that does not allow the conclusion that there is no increased risk. A fair reading is that one can not exclude that there is no effect. Rule 403. Probative value is outweighed by the prejudice. Testimony will confuse the jury into believing that the results demonstrate that there is no increased risk when it is nothing more than a failure to exclude no risk.
6:19	For example, gabapentin (shown by the red square) had an odds ratio of 1.57, but the confidence interval was 0.12 to 47.66 showing that there was not a statistically significant increased risk for suicidality with gabapentin, that is, the probability of having a suicidal thought on gabapentin or placebo is the same because the confidence interval includes the value 1.0.	Rule 702. Dr. Gibbons statement does not comport with generally accepted practices. Although the result for gabapentin is not statistically significant, that does not allow the conclusion that there is no increased risk. Rule 403. Probative value is outweighed by the prejudice. Testimony will confuse the jury into believing that the results demonstrate that there is no increased risk when it is nothing more than a failure to exclude no risk.
8:7	It is my opinion, to a reasonable degree of scientific certainty, that if lamotrigine and topiramate had never been part of this analysis, FDA would not have found that AEDs increase the risk for suicidality. If the study contained only these 9 drugs, and not lamotrigine and topiramate, there would never have been an Alert or an AC meeting or a new warning.	Lack of foundation, speculative. Dr. Gibbons is speculating on what the FDA would have found or not found. Dr. Gibbons has no idea of the deliberative process of the FDA and what other sources of information might have been relied upon.

8:16	This is sign of a really safe drug.	Rule 702. Statement goes beyond the scope of Dr. Gibbons' expertise and expert disclosures. Dr. Gibbons has not demonstrated any reliable methodology in arriving at this statement. Rule 403. Prejudice outweighs the probative value.
8:16	By throwing out all of the zero event studies it makes it appear that a much smaller group of patients was studied, and that a difference between 2 suicidal thoughts on drug and 1 on placebo is meaningful. Which it clearly is not.	Rule 702. Dr. Gibbons fails to use any reliable methodology to reach this conclusion. He cannot demonstrate that such a process leads to the result he claims.
9:19	Furthermore, these data make it clear that for gabapentin, there is no increased risk of suicidality.	Rule 702. Dr. Gibbons' statement does not comport with generally accepted practices. Although the result for gabapentin is not statistically significant, that does not allow the conclusion that there is no increased risk. Rule 403. Probative value is outweighed by the prejudice. Testimony will confuse the jury into believing that the results demonstrate that there is no increased risk when it is nothing more than a failure to exclude no risk.
9:21	Because suicidal thinking and behavior are rare events, and because FDA included 11 drugs that are very different with very different indications and types of underlying studies, it is wrong to conclude that the findings from this study are "generally consistent."	Rule 702. Goes beyond Dr. Gibbons' expertise as a biostatistician. Lack of foundation.

10:11	To illustrate my point, applying the combined results of the meta-analysis to gabapentin would be like taking a baseball team's batting average and using it to draw conclusions about the batting average of an individual player. A baseball team can have some very good hitters and some very bad hitters, and the team batting average is a combination of all of the player's batting averages and tells us very little about the batting averages of the individual players. For example, if you put me on a team with a lot of very good professional baseball players, the team batting average is likely to be high, but that does not change the fact that I would not connect with a single pitch. So, combining gabapentin data in the same way with other antiepileptic drugs with individually elevated risk, does not reliably tell us anything about gabapentin individually.	Relevance, prejudice outweighs probative value. Dr. Gibbons' example does not apply to the situation here. The FDA's statements are based upon statistics with confidence intervals and there statements are based upon the confidence intervals including the overall estimates of risk. Dr. Gibbons' analysis is trying to compare individual numbers that do not have confidence intervals to say they are different. Such a comparison to the FDA analysis is meaningless and will confuse the jury.

10:21	My fourth opinion criticizing the FDA meta-analysis is that the conclusions of increased risk do not apply to all patients. This gives rise to additional serious concerns regarding the consistency of these data. [SHOW DEMONSTRATIVE: DO FDA's CONLCUSIONS APPLY TO THESE GROUPS]. First, for studies conducted in North America, there was no signal for a significant association between antiepileptic drugs and suicidality (OR=1.38, CI=0.90-2.13). Second, for patients treated for psychiatric indications, there was no signal for a significant association between antiepileptic drugs and suicidality (OR=1.51, CI=0.95-2.45). Third, for inpatients, there was no signal for a significant association between antiepileptic drugs and suicidality (OR=1.42, CI=0.40-5.62). Fourth, for females, there was no signal for a significant association between antiepileptic drugs and suicidality (OR=1.39, CI=0.85-2.35). These subgroup analyses that were performed by FDA, are inconsistent with their conclusion that the data show a consistent picture of increased risk of suicidality for all antiepileptic drugs.	Rule 702. Dr. Gibbons' statement does not comport with generally accepted practices. Although the results for these groups are not statistically significant, that does not allow the conclusion that there is no increased risk. A fair reading is that one can not exclude that there is no effect. Furthermore, Each of these results is consistent with the FDA's overall point estimate of 1.80. Dr. Gibbons insistence that these results are not consistent is not based upon any reliable methodology. Rule 403. Probative value is outweighed by the prejudice. Testimony will confuse the jury into believing that the results demonstrate that there is no increased risk when it is nothing more than a failure to exclude no risk.
11:13	I do not have an opinion one way or another as to whether gabapentin is GABAergic. Although FDA's analysis did look at different mechanism classes of drugs to evaluate the risk of suicide, FDA unfortunately put topiramate, which had the most events, in all of the pharmacologic groups.	Rule 702. Dr. Gibbons admits he has no opinions on pharmacology nor is he qualified to do so. Yet he finds it "unfortunate" that the FDA included topiramate in the GABAergic class. Rule 403. Prejudice outweighs probative value. Jury is likely to be influences by the term "unfortunate" which lacks any basis.

14:10	and then the journal concluded the study was reliable and of scientific importance for publication.	Lack of foundation, hearsay. Plaintiff admits the journal accepted the paper for publication. Dr. Gibbons has not provided any basis for the statements that the journal found the paper to be reliable or that it was scientifically important.
17:5	It is my opinion, to a reasonable degree of scientific certainty, these data show that not only do AEDs *not* increase the risk of suicide behavior, but if anything, there may be a reduced risk for suicide attempt in these patients. That is, there may be protective effect of AEDs for suicide attempt.	Rule 702. These statements fail to meet comply with any generally accepted methodology. First, Dr. Gibbons' statement that AED's do not increase the risk does not follow from his data. His data did not show an increased risk. That does not mean that there is no increased risk. Such conclusions can not be reached from studies such as Dr. Gibbons' Bipolar study. Given the limitations outlined by Dr. Gibbons himself in his paper and discussed by Plaintiff's expert Dr. Greenland, Dr. Gibbons should only be allowed to state that his study did not find an increased risk. Second, Dr. Gibbons' statements that AED's may be protective are speculative on their face and do not meet the standards of Rule 702. Dr. Gibbons, as discussed in his own paper, and further discuss by Dr. Greenland, identifies several alternative reasons for his results and uses no reliable methodology to exclude these alternative causes, thus the speculative nature of his statements. Third, Dr. Gibbons, despite his representations in his paper, did not obtain patient prescription data for many other common psychoactive drugs such as Xanax, nor any pain medications which are commonly used. Lastly, Dr. Gibbons' own testimony demonstrate that he does not really know if the drugs are responsible for the

		decrease he observes: Gibbons, Robert V3 3/5/2009 page 930 14 Q. Okay. That's fine. 15 Just like with the bipolar analysis 16 where you said you could not conclude that the 17 AEDs cause a protective effect, is that -- is 18 that the same -- can you say the same thing in 19 terms of the gabapentin study that you did in 20 your expert report? 21 MS. McGRODER: Object to form, misstates -- 22 that misstates his testimony. 23 BY THE WITNESS: 24 A. I think that -- I mean, if what you page 931 1 are asking me is would I on the basis of either 2 the bipolar analysis or the gabapentin analysis 3 indicate that there is an unequivocal causal 4 protective effect of gabapentin, the answer is, 5 no, I couldn't draw that from -- you know, these 6 are observational data. There are some other 7 alternative explanations. 8 I think that it may be possible to do 9 so through sensitivity analyses through 10 additional analyses, but I don't think anything 11 that -- I would not state that I believe that the 12 significant decreases that we are seeing in off 13 drug, on drug, predrug, post-drug are necessarily 14 a causal effect of the drug. 15 There are other potential 16 explanations, and until those potential 17 explanations are adjusted for, I wouldn't state 18 that there is a causal protective effect. Rule 403. Prejudice outweighs probative value. Jury is likely to become confused by the speculative nature of Dr. Gibbons' statements.

17:7	The results of my study on bipolar patients addresses the theory in the case expressed by plaintiffs' experts Drs. Kruszewski, Trimble, Glenmullen and Blume that individuals who have suicide risk are "vulnerable" and "susceptible" to the effects of gabapentin and other AEDs. This entire study is on that group of individuals that - if plaintiffs' experts' theory were correct - these patients would be the most vulnerable to AEDs like gabapentin. Published studies show that patients with bipolar disorder have the highest risk of suicide behavior out of all psychiatric disorders. If there was ever a group to test a "vulnerable subpopulation" theory in, this is it. Furthermore, the secondary analysis in prior attempters is an even higher risk sample. My study shows the opposite. Gabapentin does NOT increase the risk of suicide behavior in people at the highest risk for suicide. And in fact, "vulnerable" people at the highest risk of suicide behavior had a statistically significantly lower risk after taking AEDs, including gabapentin.	*See* objections to 17:5 In addition: Rule 702. Goes beyond Dr. Gibbons' expertise in assessing the relationship of bipolar patients to suicide.
18:5	Not only did I adjust for other drugs that were taken, such as antidepressants, antipsychotics, and other antiepileptics, I looked at a subgroup of patients who ONLY took gabapentin, to rule out any confounding effects of patients taking other psychiatric medications.	Rule 702. By his own admission, Dr. Gibbons did not obtain all other psychiatric medications. He limited his data to antidepressants, antipsychotics, and antieplieptics. He did not obtain data for anxiolytics (Xanax), pain medications, stimulants (Ritalin), and hypnotics (Phenobarbital). *See generally* March 19, 2010 report of Dr. Greenland. Dr. Gibbons failure to obtain these data fails to meet the tests of reliability under Rule 702.

18:13	I found that the risk of suicide attempt in gabapentin patients prior to treatment is low 30/100,000 PY, but it is cut almost in half after taking gabapentin (16/100,000 PY).	Lack of foundation . According to table from Dr. Gibbons' report of 1/8/2010, the rate for gabapentin before is 348/100,000 PY and 345/100,000 PY after.
18:19	Gabapentin significantly decreases suicide attempt rates in these more severely ill patients with psychiatric illnesses, which is shown in the top three blue circles. These data suggest that there may be a possible protective effect in psychiatric patients taking gabapentin.	*See* objection to 17:5 In addition: Rule 702. Dr. Gibbons has demonstrated no reliable methodology in his conclusion that gabapentin is the cause of the reduction he observes.
19:17	The findings from my study are dramatic for gabapentin - the gabapentin patients were at 6 times less risk of suicide attempt after taking gabapentin. This finding shows that if anything, gabapentin protects against risk of suicide attempts.	*See* objection to 17:5
19:19	Gabapentin does not increase the risk of suicide attempt - especially in patients who the plaintiffs' experts say are "vulnerable" or "the susceptible minority". In fact, in those patients with psychiatric illness - major depressive disorder and bipolar disease - gabapentin treatment was associated with significantly *lowered* risk of suicide attempt.	*See* Objection to 17:5 In addition: Rule 702. Goes beyond Dr. Gibbons' expertise in assessing the relationship of bipolar patients to suicide.

20:4	Also, my findings for gabapentin are in line with the FDA data for gabapentin alone, which show that gabapentin does NOT increase risk of suicidality.	Rule 702. Dr. Gibbons' statement does not comport with generally accepted practices. Although the result for gabapentin is not statistically significant, that does not allow the conclusion that there is no increased risk. Rule 403. Probative value is outweighed by the prejudice. Testimony will confuse the jury into believing that the results demonstrate that there is no increased risk when it is nothing more than a failure to exclude no risk.
20:6	Based on all of the evidence that I have reviewed, and the data that I have personally analyzed, it is my opinion that there is no increased risk of suicidal thinking and behavior for gabapentin overall, and if anything, there may be protective effects for psychiatric patients who are at increased suicidal risk.	*See* Objection to 17:5
20:9	Because no signal has been identified for increased risk of suicidality for gabapentin, there was never any reason for Pfizer to warn physicians of this non-existent risk.	Rule 702. Beyond the scope of Dr. Gibbons' expertise and report which is limited to statistical issues. Requires opinions on pharmacovigilance, regulatory requirements, interpretation of clinical signals, all of which are outside of Dr. Gibbons' expertise.
Slide 18	Entire Slide	No connection to Dr. Gibbons' witness statement

8.

Alex Ruggieri, M.D.

Plaintiff objects to Dr. Ruggieri's report in general. The majority of Dr. Ruggieri's statement is devoted to a recitation of the history of the safety of Neurontin and does not involve the application of his expertise. Rather, his chronologies are "merely a 'narrative of the case which a juror is equally capable of constructing.'" *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 551 (S.D.N.Y. 2004) (expert's "history of Rezulin" was inadmissible). In addition, "[s]uch material, to the extent it is admissible, is properly presented through percipient witnesses and documentary evidence." *Id.*

In *In re Prempro Prods. Liab. Litig*., 554 F. Supp. 2d 871 (E.D. Ark. 2008), the Court held that "[h]aving an expert witness simply summarize a document (which is just as easily summarized by a jury) with a tilt favoring a litigant, without more, does not amount to expert testimony." *Id*. at 887. Similarly, in *Fisher v. CIBA Specialty Chems. Corp.*, 238 F.R.D. 273, 281 (S.D. Ala. 2006), the court expressed its opinion regarding such factual narratives:

> After studying [plaintiff's regulatory expert's] report, the Court shares defendants' concerns. The document reads like the fact section of a brief, not the report of an expert witness. . . . [The expert's] statements of alleged fact do not appear to benefit from, or to be based to any extent on, [his] status as a regulatory expert.

Such expert testimony "invade[s] areas that require[] no expert testimony," and is therefore "inappropriate 'expert' testimony." *Prempro*, 554 F. Supp. 2d at 887.

With respect to Dr. Ruggieri's statement, Dr. Ruggieri renders an opinion on page 8 that the company complied with all safety requirements. He then goes from page 8 line 9 through page 14 line 17 reciting fact after fact without rendering any opinions. Then he simply states on page 14 line 17 that the company never saw a signal for suicidality. In the interim, Dr. Ruggieri fails to tie any of these facts to a specific opinion. Other examples runs from pages 14-19 and 19-22.

Dr. Ruggieri's testimony about the Neurontin safety chronology will not "assist the trier of fact," as required by Rule 702. The jury does not need expert testimony to interpret such evidence because it does not relate to "scientific, technical or other specialized knowledge." Fed. R. Evid. 702. A n expert should not "'supplant the role of counsel in making argument at trial, and the role of the jury in interpreting the evidence.'" *Prempro*, 554 F. Supp. 2d at 887 n.86 (quoting *Rezulin*, 309 F. Supp. 2d at 551).

Dr. Ruggieri's narrative chronologies are therefore not admissible because he fails to apply any expertise.

In addition, Plaintiff makes the following objections to specific portions of Dr. Ruggieri's statement.

Page: Line	***Statement***	***Objection***
8:5	Based upon my review of the record in this case, I am familiar with Pfizer's and Parke-Davis's pharmacovigilance activities regarding Neurontin, and it is my opinion that the company complied with regulatory and safety standards regarding pharmacovigilance activities sufficient to satisfy global regulatory requirements.	Lack of foundation. Defendants failed to produce documents from the safety surveillance activities during the Parke-Davis era other than periodic reports. Dr. Ruggieri has no way to know of the safety activities within the company during the Parke-Davis era.
10:12	whereas the term "suicidal" in the modified COSTART corresponded to "suicide attempt" in MedDRA, with preservation of the concept	Lack of foundation. Reference not located in Defendants' Exhibit 7399 or 7400. (Costart Manual).
15:10	Dr. Blume concedes that at least by June 2003, the publicity was such that the adverse event databases were biased by notoriety or publicity. It is my opinion that the adverse event report database for Neurontin was influenced by litigation and subsequent solicitation of reports, the surrounding publicity concerning Neurontin, as well as publicity surrounding safety issues of other medications during this time period.	Cumulative of testimony of Dr. Weiss-Smith. Rules 702-704. Dr. Ruggieri does not employ any reliable methodology to conclude that publicity surrounding other drugs stimulated Neurontin reporting. He also fails to demonstrate any reliable methodology to conclude that there was any solicitation of reports and what influence these might have had on the database. Lack of foundation, prejudice outweighs probative value. Dr. Ruggieri does not limit his opinion to the post June 2003 era and has no foundation to include time period before this. There is no reliable evidence that before June 2003 there was any publicity bias. Lastly, this opinion was not disclosed in accordance with Rule 26 and deadlines issued by the Court.
20:17	The FDA responded to my inquiry in an	Authenticity

	email dated April 1,2008 that is labeled Exhibit 7392 and is shown on the current slide, [SHOW POWERPOINT HERE (FDA EMAIL TO RUGGIERI: CONTROLLED TRIALS THE ONLY WAY TO ESTABLISH WHETHER AEDS ARE RESPONSIBLE FOR SUICIDE)] and stated that "the agency does not believe that spontaneous post-marketing reports can be interpreted appropriately in this situation. Patients taking these drugs have a high background rate of suicidal thoughts/behaviors, and it is not possible to tell from AERS reports, whether the drug caused them." The FDA told me that "in the agency's view, the only way to establish whether or not the drugs are responsible for suicidality is to analyze controlled trial data."	Plaintiff objects to the authenticity of Defendants' Exhibit 7392. A document may be authenticated by "appearance, contents, substance, internal patterns, or other distinctive characteristics, taken in conjunction with circumstances." Fed. R. Evid. 901 (b)(4). A district court has discretion to determine authenticity. *United States v. Siddiqui*, 235 F.3d 1318, 1322 (11th Cir. 2000). The document in question lacks any markings from the FDA and does not even come from the email account of Dr. Dobbs which is listed on the Health and Human Services Website as "donald.dobbs@fda.hhs.gov." Furthermore, Dr. Dobb's mailing address and phone numbers are not provided at the bottom of the email as is customary for other emails from the FDA. As such, it is unclear who at the FDA, if anyone, actually sent the email in question. This is most troubling considering that the Defendant's are attempting to use this email as representing the official position of the FDA. When asked about the email at his deposition in December 2008, Dr. Ruggieri stated: Q. Did you receive this e-mail through your home computer? A. Yes. Q. Do you still have the e-mail on your home computer? A. I don't think I do. (Deposition of Alex Ruggieri, December 5, 2008, at 277-278) Dr. Ruggieri has never produced the e-mail with routing information which could settle the question of its authenticity. Defendants have been well aware of Plaintiffs' questions concerning the authenticity of this document, yet have failed to do anything. For example, they could have obtained a "red ribboned" version of the email from the FDA to validate its

		authenticity. Hearsay. Aside from its authenticity, the document is inadmissible hearsay. The document purports to set forth the FDA's position regarding the usage of adverse event reports in the context of suicidality. According to the e-mail, Dr. Dobbs allegedly provides the position of the FDA. It is unclear that Dr. Dobbs is authorized to provide official policy determinations of the FDA. Since the defendants are putting forth this email to prove that the FDA does not believe that adverse events can be used to determine causality, the document is classic hearsay. The email does not fall under any of the hearsay exceptions as it does not satisfy the requirements of FRE 803(6) or 803(8). It is therefore inadmissible hearsay and not relevant to any issue herein, especially the FDA's position on whether information in the AER's can cause increased suicidal thoughts or behavior in patients taking antiepileptic drugs. Prejudice outweighs probative value.
20:14	The FDA again commented that postmarket data are not appropriate for this type of analysis at the Joint Advisory Committee Meeting regarding AEDs and suicidality on July 10, 2008. At this meeting, the FDA said that postmarketing spontaneous adverse event data are not appropriate for a study of suicidality in the population of patients taking AEDs, because such patients have a high background rate of suicide. Dr. Katz stated that the FDA "had long ago decided that postmarketing data are not the right data to look at . . . where there is a high background rate of suicidality so	Cumulative with Dr. Arrowsmith-Lowe 23:22. Lack of foundation. There is no evidence that the FDA concluded the postmarketing adverse event reports were unreliable. Dr. Ruggieri misstates Plaintiff's opinions when he claims that postmarketing adverse event reports are the sole basis for Plaintiff's claims. Prejudice outweighs probative value.

	defined in these populations," and that for this type of analysis, "postmarketing data is uninterpretable, and that is why [the agency] went to placebo-controlled trials." This demonstrates FDA currently recognizes and understands that patients with these diseases and disorders, including neuropathic pain, have an increased risk of suicidal events, which occur by virtue of these conditions themselves regardless of treatment. A transcript of this Joint Advisory Committee Meeting is **Exhibit** 7257. The FDA's repeated statements regarding the unreliable and un-interpretable nature of postmarketing data are contrary to the assertions made by the plaintiffs' experts, who use postmarket adverse event report data entirely and solely as a basis to assert in a link between Neurontin and suicidality.	
22:6	This June 2006 analysis, which is labeled **Exhibit 7207,** included 8829 patients, and "[u]sing the search strategies stipulated by FDA for "Possibly Suicide-Related" adverse events that occurred during the double-blind phase of treatment or within one day of beginning of taper, switching or stopping treatment, 336 possible cases out of 8829 patients were identified." As shown in this slide from the June 2006 analysis, **[SHOW POWERPOINT HERE (NEURONTIN PLACEBO-CONTROLLED CLINICAL TRIAL** DATA)] a further analysis and classification of the 336 possible cases revealed no cases of completed suicide, no cases of attempted suicide and no cases of "preparatory acts towards imminent suicidal behavior" among Neurontin users. There were two suicidal ideation cases in Neurontin-treated patients, and one suicidal ideation in placebo-treated patients. I	Cumulative with Dr. Arrowsmith-Lowe 24:7.

	have formed an opinion, to a reasonable degree of medical and scientific certainty, as to whether these data suggest an increased risk for suicidal behaviors in Neurontin-treated patients. It is my opinion that these data support the conclusion that Neurontin use does not pose an increased the risk of suicidal behavior or thinking and that Neurontin neither causes nor is associated with an increased risk of suicidal behavior and thinking, completed suicide, suicide attempt, suicide gesture and suicide ideation.	
23:5	Up until December of 2005, the Neurontin label contained the terms "suicidal" and "suicide gesture" as "infrequent" and "rare" adverse events, respectively. I have treated patients that I have considered to be suicidal or to show suicide gestures. As a clinician, "suicidal" is a very broad term that encompasses suicide gesture, suicide ideation, suicide attempt or suicide. A suicidal patient has either demonstrated or had the potential of demonstrating suicide or suicide related behavior. "Suicide gesture" is any act, inclination, hint, verbal threat, explicit or implicit that could suggest a risk for a suicide attempt. This includes features or manifestations of the patient that would indicate suicidal ideation. As a clinician and an expert in drug safety, it is my opinion that the Neurontin labeling adequately conveyed necessary information to prescribers regarding risks and benefits of Neurontin, and suicide behavior and depression were appropriately described in the label. On October 20, 2005, the FDA sent an e-mail, which is **Exhibit 7201,** requesting that Pfizer make a few minor changes to the Neurontin label. Specifically, the FDA asked that Pfizer delete "suicidal" and "suicide gesture" and add "suicide attempt" as an infrequent event and "suicide" as a rare event in the epilepsy section. In an October 27, 2005 e-mail from the FDA, which is labeled **Exhibit**	Cumulative with Dr. Arrowsmith-Lowe 21:11.

	7202, the agency explained that "suicidal" should be deleted because the FDA viewed it as an adjective and thought it unclear without any noun following it. As for "suicide gesture," the agency said it was a less clear term than "suicide attempt." As reflected in **Exhibit 7203,** which is an e-mail Pfizer sent to the FDA on November 18, 2005, the company explained that "suicide gesture" was not intended to encompass suicide attempt, but instead reflected self-injurious behavior associated with no intent to die. As further explained in the email, "suicide gesture" describes behavior that is intended to effect change in others or the environment or intended to relieve distress, such as superficial cuts or scratches, hitting/banging, or bums. The term "suicidal," which had been included in the Neurontin label since 1993, was taken from Warner-Lambert's modified COSTART dictionary and included "attempted suicide" and "suicide ideation." A few days later on November 22, 2005, the FDA sent the company another e-mail, which is labeled **Exhibit 7204** and shown on this slide **[SHOW POWERPOINT HERE** (FDA'S **MINOR LABELING CHANGE REQUEST)],** advising that the company should "proceed with the minor labeling changes."	
25:4	Dr. Blume's report repeatedly aggregates or "lumps" multiple adverse events into a category called "Psychobiologic Adverse Events" - there is no explanation or medical basis provided in the Blume report of any medical or physiological semantic relationship between this aggregate concept and the concept of suicidality, nor would she by virtue of her qualifications, including her lack of medical training, be able to provide any.	Lack of foundation. Dr. Blume used Defendants' own terms for "psychobiologic". Dr. Ruggieri's comment on Dr. Blume's qualifications lacks foundation as she has done this exact task innumerable times over the past 25 years. Dr. Ruggieri can not point to any scientific or regulatory source that establishes she must be a medical doctor to render these opinions.

		Prejudice outweighs probative value.
Slide 12	Entire slide	*See* authenticity, at 20:17.

9. Sheila Weiss-Smith, Ph.D.

Slide 18	Entire Slide	No connection to Dr. Gibbons' witness statement

Page: Line	***Statement***	***Objection***
4:18	Fourth, the information in the AERS database for gabapentin and suicide is unreliable and therefore uninterpretable.	Opinion not disclosed in accordance with the requirements of Fed. R. Civ. P. Rule 26 nor Orders of the Court. Lack of foundation
8:14	As I will explain later, publicity, including plaintiffs' counsels' advertising for clients to sue Pfizer over Neurontin and other litigation activities likely played a major role in the reporting of suicidal behavior events for Neurontin.	Rule 702. Beyond the scope of Dr. Weiss-Smith's expertise. No reliable methodology to determine that attorney advertising played a major role in reporting of adverse events. Lack of foundation. No evidence that advertising played any role in the reporting. Relevance, prejudice outweighs probative value. A signal for suicidal behavior arose prior to publicity bias, and all parties' experts acknowledge that publicity bias did not exist until after second half of 2003, thus any evidence regarding Adverse Event reports after the second half of 2003 is not relevant.

Page: Line	***Statement***	***Objection***
9:5	That is where my analysis was to stop - I did not conduct any clinical evaluation of the AERS data for a potential signal, as that takes clinical training and expertise that neither I nor Dr. Blume possess.	Rule 702. Because Dr. Weiss-Smith is unqualified to render opinions on signals, she is also unqualified to render and opinion that Dr. Blume, who has already been subjected to *Daubert* scrutiny in the MDL, is unqualified, contrary to the finding of the Court. Prejudice outweighs probative value.
10:9	It is important to point out that Dr. Blume did not perform either a statistical or a clinical evaluation of the adverse event data she summarized. So, it is my opinion that what she claims to have found from the AERS database is not a "signal." This is because she did not perform the data mining analysis correctly. But, even if you assume that the analysis was performed correctly, she cannot say there is a signal because she was not able to clinically review the data.	Cumulative with Dr. Arrowsmith-Lowe 30:13. Lack of foundation. Ignores Dr. Blume's entire report which is a clinical evaluation of the signals. Rule 702. Because Dr. Weiss-Smith is unqualified to render opinions on signals, she is also unqualified to render and opinion that Dr. Blume, who has already been subjected to *Daubert* scrutiny in the MDL, is unqualified, contrary to the finding of the Court
13:2	You will note that after mid-2003 the graph is shaded to show when the adverse event data base was corrupted by attorney advertising and publicity surrounding the litigation.	Plaintiff objects to Charts 10, 11, 12, 14, and 15 because they show the publicity bias as including all of 2003 which is inconsistent with the witness' statement. Rule 702. Beyond the scope of Dr. Weiss-Smith's expertise. No reliable methodology to determine that attorney advertising played a major role in reporting of adverse events. Lack of foundation. No evidence that advertising played any

Page: Line	***Statement***	***Objection***
		role in the reporting. Relevance, Prejudice outweighs probative value. A signal for suicidal behavior arose prior to publicity bias, and all parties' experts acknowledge that publicity bias did not exist until after 2nd half of 2003, thus any evidence regarding Adverse Event reports after the 2nd half of 2003 is not relevant.
13:6	What is remarkable is a dramatic jump in the number of direct reports in the year 2005. From 1994 - 2004, the number of direct reports increased from 28 to 130. From 2004 - 2005, the number of direct reports jumped to 595 reports. Thus, in just one year, the number of direct reports increased as much as it had over the previous 10 years. In the AERS database, direct reports typically account for just 10% of all reports. To explore further and understand why there was a sudden and dramatic increase in direct reports in 2005 with gabapentin as the suspect agent I looked at the distribution of reports each quarter (based on report date) by the patient outcome. [SHOW DEMONSTRATIVE: GABAPENTIN REPORTS BY REPORT TYPE - BY QUARTER]. This slide shows that there was a very large number of deaths reported (n=315) in the first quarter of 2005. Over the entire time of marketing, the overall proportion of deaths was less than five percent, but in the first quarter of 2005 it was 20%. This plot does not mean that all of these people died in the first	Relevance. Witness has stated that the data after June 30, 2003, is not reliable for any signal detection opinions. No Plaintiff witness has expressed that this data is reliable. Sole purpose is to inflame the jury that lawyers are responsible for some of the adverse event reports ***after*** the death of Mr. Smith. Prejudice outweighs the probative value.

Page: Line	*Statement*	*Objection*
	quarter of2005; this only shows report date, not event date. In an attempt to try to explain these findings, I examined individual events by report date. I found it unique and suspicious that a large number of reports were all entered into AERS within a 4 day period in 2005. Also, the reports were unusually "clean" with 1 or 2 reaction terms listed, when an infinite number are allowed by FDA; the average is 4 per report. Most, if not all, listed as "Neurontin" where reports from other time periods have both Neurontin and gabapentin. Most had only Neurontin listed - without listing any other medications - which is unusual for Neurontin users. These reports are highly suspicious and very unreliable for analysis purposes. This demonstrates that these peaks after the introduction of litigation and associated publicity were stimulated and therefore not valid for any analytical purpose. Dr. Blume has conceded that after 2003 these reports are impacted by publicity.	

Page: Line	***Statement***	***Objection***
15:1	Although Dr. Blume looked at many events in addition to completed suicides and suicide attempts, I chose to look at only completed suicides and suicide attempts. These terms are less ambiguous than the additional terms that Dr. Blume used in her analysis. Completed suicide and suicide attempt are clearly serious under the regulatory definition, where serious is based on patient outcome and not the reaction terms coded.	Rule 702. Goes beyond Dr. Weiss-Smith's expertise. She admits she is not qualified to interpret clinical signals. She is not a regulatory expert. While completed suicide is by definition serious, suicide attempts may or not be serious depending on an individual determination by the reporter. Furthermore, Dr. Weiss-Smith is not qualified to assess whether the terms selected by Dr. Blume are more ambiguous than her own. Lack of foundation. Dr. Weiss-Smith ignores suicide attempt reports that are coded by reporters as non-serious.
15:12	In the field of pharmacoepidemiology, a PRR greater than 2, along with several other statistical criteria, is a commonly used statistical threshold to define an alert. [SHOW DEMONSTRATIVE: PRR FOR GABAPENTIN: COMPLETED SUICIDE AND SUICIDE ATTEMPT]. This slide shows the results of an analysis comparing completed suicide or suicide attempt for gabapentin to those events reported for all other drugs. As shown in this slide, completed suicide and suicide attempt did not reach the threshold of2.0 until after 2005. As shown by the shading, this occurs after the publicity bias generated by litigation activities. This means that there is no data mining alert for suicide with Neurontin using the AERS data until that time.	Rule 702. Dr. Weiss Smith used faulty methodology when she created this slide rendering the chart misleading. By her own admission, the PRR is undefined for completed suicide in the time period before 1998. Yet the chart as presented shows the PRR as zero. This misleads the jury into believing that the were no suicides in gabapentin at the same time that there were some in the background. furthermore, Dr. Weiss-Smith's presentation fails to meet any reliable methodology by including data that can not possibly have any events and shifting any signals into later time periods.

Page: Line	***Statement***	***Objection***
16:1	You can see from this plot that the PRR does eventually rise above 2. It is almost certain that the PPR increased, in part, as a result of the 258 direct reports submitted in first Quarter 2005 by attorneys, as confirmed in a letter from Mr. Finkelstein (plaintiffs' attorney) to Dr. Katz of FDA that he submitted these 258 reports. [SHOW DEMONSTRATIVE: 4/1212005 LETTER FROM KATZ TO FINKELSTEIN]. This is a good example of how bias, here created by plaintiffs' attorneys who submitted a large number of stimulated reports, can decrease the usefulness of the data in the AERS database to identify signals. There is evidence of significant bias in the reporting of suicides to the FDA's adverse event database, which can be attributed to the plaintiffs' attorneys. So, basically, plaintiffs' attorneys have created this very "signal" in the AERS database. As highlighted in this letter from FDA to plaintiffs' counsel, FDA recognized the flaws in the FDA AERS database and the uninterpretable nature of spontaneously reported suicide events. I agree with FDA's conclusion as to the problems with the use of adverse event reports for this purpose.	Relevance. Witness has stated that the data after June 30, 2003 is not reliable for any signal detection opinions. No Plaintiff witness has expressed that this data is reliable. Sole purpose is to inflame the jury that lawyers are responsible for some of the adverse event reports ***after*** the death of Mr. Smith. Prejudice outweighs the probative value. Lack of foundation. Neither the letter, nor the chart states that there are flaws in the AERS database. Furthermore, the letter does not state that the spontaneous reports are uninterpretable. Dr. Weiss-Smith's characterization of the letter is incorrect. Cumulative with Dr. Arrowsmith-Lowe 22:17.
17:1	Plaintiffs have suggested that there was no notoriety bias in reporting of suicides based solely on the timing of plaintiffs' counsel's reporting of suicide events to FDA. However, this ignores the fact that there are many other people and entities reporting events to the FDA. Indeed, the evidence suggests that there was significant "notoriety bias" surrounding the reporting of suicide-related adverse events during the period in question. [SHOW DEMONSTRATIVE: COMPLETED SUICIDE REPORTS	Rule 702. Dr. Weiss-Smith uses no reliable methodology when she concludes that notoriety affecting one class of drugs, SSRI's, has anything to do with the reporting of adverse events for Neurontin. She can cite to no reliable source for this opinion, nor are her computations anything more than coincidental observations. Her opinion is nothing more than *ipse dixit*.

Page: Line	*Statement*	*Objection*
	NEURONTIN VERSUS ALL DRUGS]. This slide shows the number of completed suicides in the FDA AERS database for all drugs (red line) and for gabapentin only (blue line). This shows that the number of suicides (completed suicides) reported to the FDA regardless of drug more than doubled from 1027 in 2002 to 2119 reports in 2003, while suicide reports mentioning gabapentin increased 2.3-fold from 40 in 2002 to 92 in 2003. The reporting of completed suicides (all drugs) appears to have peaked in 2005 at 2899 reports. Also during this same time period both the FDA and European regulators issued warnings about a possible link between SSRI antidepressants and suicidal behaviors in children and adolescents in 2003 and FDA held an advisory committee meeting on this subject in early (February 3rd) 2004. Such events are known to stimulate reporting. This is an important example as to why an epidemiologist needs to consider much more than simply raw counts of adverse events for a single drug that gives the appearance of a peak or spike on a graph. While visually interesting, such peaks and spikes of adverse event reports need to be considered carefully and in the appropriate context. As this graph shows, Neurontin is no different than what is being reflected in the entire AERS database with regards to reports of suicide.	Lack of foundation Prejudice outweighs probative value. Relevance.

Page: Line	***Statement***	***Objection***
Slides 10, 11, 12, 14, and 15	Publicity shading	Misrepresents the testimony of Dr. Weiss smith that the publicity started in the second half of 2003. Rule 702. No reliable basis for concluding that there was a publicity influence in the first half of 2003.
Slide 12	Entire Slide	Rule 702. Dr. Weiss-Smith's chart showing the PRR for Neurontin and completed suicide before 1998 as zero misrepresents that the PRR cannot be calculated at that point. Probative value outweighs the prejudice.

Dated: May 12, 2010

Respectfully submitted,

THE LANIER LAW FIRM, P.L.L.C.

By: **/s/ W. Mark Lanier**

W. Mark Lanier, Esq.
Dara G. Hegar, Esq.
Ken S. Soh, Esq.
Maura Kolb, Esq.
Robert Leone, Esq.
126 East 56th Street, 6th Floor
New York, NY 10022

- and -

FINKELSTEIN & PARTNERS, LLP

By: **/s/ Andrew G. Finkelstein**

Andrew G. Finkelstein, Esq.
Kenneth B. Fromson, Esq.
1279 Route 300, P.O. Box 1111
Newburgh, NY 12551

- and -

BARRETT & ASSOCIATES, P.A.

By: **/s/ Charles F. Barrett**

Charles F. Barrett, Esq.
BPR # 020627
6518 Highway 100, Suite 210
Nashville, TN 37205

Attorneys for Plaintiff Ruth Smith

CERTIFICATE OF SERVICE

I hereby certify that on this the 12th day of May, 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

Aubrey B. Harwell, Jr., Esq.
W. David Bridgers, Esq.
Gerald D. Neenan, Esq.
Robert A. Peal, Esq.
Neal & Harwell, PLC
2000 One Nashville Place
150 Fourth Avenue, North
Nashville, TN 37219

Prince C. Chambliss, Jr., Esq.
Evans & Petree, PC
1000 Ridgeway Loop Road, Suite 200
Memphis, TN 38120

Mark S. Cheffo, Esq.
Catherine B. Stevens, Esq.
Skadden, Arps, Slate, Meagher & Flom LLP
Four Times Square
New York, NY 10036

Andrew Howell Myers, Esq.
James Ernest Hooper, Esq.
Stephen Ernest Oertle, Esq.
Wheeler Trigg O'Donnell LLP
1801 California Street, Suite 3600
Denver, CO 80202-2617

Faith E. Gay, Esq.
Quinn, Emanuel, Urquhart, Oliver & Hedges, LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010

/s/ Andrew G. Finkelstein
Andrew G. Finkelstein